Exhibit 7

CONFIDENTIAL

EXPERT REPORT

Analysis of Distributor Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances on behalf of the City of Huntington and Cabell County, West Virginia

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Prepared by
James E. Rafalski
37637 Five Mile Road #278
Livonia, MI 48154

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I. QUALIFICATIONS AND EXPERIENCE

A. Statement of Qualifications

- 1999 graduate of Eastern Michigan University with a degree in Public Administration.
- 26 years of law enforcement experience.
- Retired in 2002 as an Executive Lieutenant with the Romulus Police Department.
- Drug Enforcement Administration Diversion Investigator assigned to the Detroit Divisional Office from September 2004 through retirement in June 2017. Diversion Investigators are responsible for several different types of investigations including regulatory investigations, state-action related investigations, pre-registration application investigations, civil investigations, administrative investigations, and criminal investigations. In 2011 Detroit DEA management restructured the responsibilities of the diversion investigators in the Detroit Divisional Office. At that time, Mr. Rafalski's primary responsibility was to conduct administrative, civil, and regulatory investigations of DEA registrants.
- Successfully completed the following DEA training: Basic Diversion Investigator School (2004), Distributor Briefing/Training (2008), Advanced Diversion Investigator School (2009), Comprehensive Regulatory Investigation Training (2010), Diversion Leadership School (2011), Advanced Diversion Investigator School (2015).
- Participated as a DEA Instructor in the design and presentation of the following training programs: Task Force Officers Training and Orientation, Detroit, Michigan (January 2009), Basic Narcotics Training, Macomb Police Academy, Clinton Township, Michigan (April 2009), U.P. Prescription Diversion/Asset Forfeiture Class, Marquette, Michigan (July 2009 and September 2010), and Basic Narcotic Investigator Course, Richmond, Kentucky (May 2010). Prescription Drug Diversion, Gaylord, Michigan (2015)

B. Awards

- Maintained a performance rating of "Outstanding" from 2005 to 2016.
- Received DEA performance awards from 2009 to 2015 and in 2017.
- Received an award from the Detroit Federal Executive Board in 2013 for exemplary public service to the DEA.

- DEA Administrator's Award for the investigation of the Harvard Drug Group.

- In June of 2013 and September of 2017 he received recognition from the United States Attorney's Office, Eastern District of Michigan for the Harvard Drug Group and Mallinckrodt LLC

C. Significant Investigations

- **2004 -2008 Investigation of Dr. Leo Ognen**
  - Criminal opioid investigation related to improper prescriptions.
  - Led to the creation of prescribing database utilized in Ohio.
  - Conducted interviews with employees of pharmaceutical companies.
  - Resulted in conviction and incarceration.

- **2006 – 2011 Investigation of Dr. Sohrab Shafinia, D.O.**
  - Criminal opioid investigation of conspiracy to possess controlled substances with intent to distribute.
  - Investigation led to the identification and conviction of an organized prescription drug ring.
  - Extensive reviews of Michigan Automated Prescribing Records (MAPS)
  - Conducted interviews, surveillance, recruiting and utilizing cooperating individuals, as well as undercover activities.
  - Investigation led to the identification and conviction of the responsible pharmacist.

- **2006 – 2008 Investigation of Dr. Louis Cannella, M.D.**
  - Criminal opioid investigation related to improper prescriptions.
  - Extensive reviews of Michigan prescription monitoring program records.
  - Led to the creation of a Wisconsin prescription database.
  - Conducted numerous interviews of witnesses and defendants, surveillance, recruiting and using cooperating individuals, as well as other investigative activities.
  - Resulted in conviction and incarceration.

- **2006 Regulatory Investigation of Walgreen's, Perrysburg, Ohio**
  - Unannounced regulatory investigation related to ensuring compliance with regulations and record keeping involving controlled substances.
  - Conducted an accountability audit, record-keeping review, and security investigation.
  - Resulted in the issuance of a Letter of Admonition for inadequate SOMS.

- **2007 Regulatory Investigation of Lake Erie Medical Supply**
  - Regulatory investigation related to repackaging, relabeling and distribution of controlled substances mainly to physicians and medical offices.

- Recommended a distributor briefing at DEA headquarters in November 2008 to reiterate regulatory requirements to registrants.
- Attended the November 2008 distributor briefing presented by other Diversion Investigators.

- **2010 – 2011 Administrative Investigation of The Harvard Drug Group**
  - Conducted a review of ARCOS data to identify any unusual patterns of distribution of oxycodone to Florida pain clinics.
  - Conducted extensive review of company records and policies, controlled substance order forms, DEA Form 222s, and interviews of employees.
  - Conducted review of chargeback system.
  - Investigation led to an Order to Show Cause in June of 2010 for among other things, developing work around so as to not trigger SOMS.
  - Investigation concluded with entry of an Administrative Memorandum of Agreement that remained in effect for three years.

- **2010 – 2013 Administrative Investigation of Masters Pharmaceutical**
  - Met with and interviewed employees and initiated an on-site investigation.
  - Served several DEA Administrative subpoenas and obtained 21 customers files to review.
  - Reviewed customer files which contained customer due diligence including but not limited to: questionnaires, on-site investigation reports, written notations, utilization reports, ship to memos, SOMS information, and electronic notations.
  - Investigation concluded with the issuance of an Order to Show Cause.
  - Order to Show Cause resulted in revocation of DEA registration which was affirmed by United States Court of Appeals for the District of Columbia Circuit.

- **2010 – 2017 Administrative Investigation of Mallinckrodt L.L.C.**
  - Administrative investigation begun in response to information related to a chargeback program based on other investigations.
  - Reviewed the chargeback discount program and transactional information involved in the program, which included the purchasers name, address, type and strength of drug, and date of transaction.
  - The investigated chargeback data contained information that allowed Mallinckrodt to see the geographic distribution of their products, the volume and size of purchases.
  - Chargeback data also disclosed some pharmacies and/or practitioners utilizing multiple distributors to purchase the same product in large quantities.
  - Through an administrative subpoena requested documents related to suspicious order system and related policies, related compliance policies,

chargeback data, customer files, internal and external communications to include emails, written correspondence, and notes.

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the defendant distributors to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.[1] I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Cabell County and the City of Huntington, West Virginia. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed tens of millions of documents. I have relied upon the defendant's answers to Combined Discovery Requests as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of $300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is $500.00 per hour. I have previously provided expert testimony by deposition in *In re: National Prescription Opiate Litigation*, MDL No. 2804 (Case Track One) and in the New York State litigation, *In re Opioid Litig.*, Index No. 400000/2017. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

[1] I provide all opinions in this report with a reasonable degree of professional certainty.

II. Opinions

Based on my education, background, experience, and review of the documents produced in this matter and provided to me, my opinions, which are more fully set forth throughout this report, are as follows:

1. The Controlled Substance Act (CSA) is designed to provide for a closed delivery system related to the pharmaceutical supply chain. The CSA requires DEA registration for each member of the closed supply chain, known as a registrant. This is due to the dangerous and abusive nature of the controlled substances that flow through the pharmaceutical supply chain.

2. As a member of the closed delivery system each registrant takes on certain statutory and regulatory obligations to ensure the safety and efficiency of the pharmaceutical supply chain. These statutory and regulatory duties have remained the same sense the enactment of the CSA.

3. The pharmaceutical supply chain flows from manufacturer (labeler) to wholesale distributor and then to the end dispenser (pharmacy, hospital, practitioner). This gives the distributors a unique position in the supply chain in that they are the last checkpoint before the controlled substances go to the end dispenser.

4. Under the CSA and the implementing regulations the distributors have two significant obligations that are designed to ensure that these controlled substances do not veer outside of the closed supply chain. These statutory and regulatory obligations come from:

    - 21 U.S.C.A. § 823(b)(1); which requires the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."

    - 21 C.F.R. § 1301.74(b); which require the registrant to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Then the registrant is required to notify the DEA of all identified suspicious orders prior to shipment.

5. Each of these play a vital role in protecting the integrity of the pharmaceutical supply chain. It is up to each registrant to design a system, often referred to as a suspicious order monitoring system (SOMS), that will comply with these regulatory requirements based on the differing type of business models they choose as customers. For example, a wholesale distributor that only services hospitals would need a SOMS different from that for one who services veterinary clinics.

6. Cardinal Health, McKesson and AmerisourceBergen each failed to develop and implement a SOMS that would ensure the maintenance of effective controls against diversion. While

each of them had different systems for which they implemented each of these systems were either faulty in their design or in the manner they were operated.

7. Cardinal Health, McKesson and AmerisourceBergen each failed to develop a comprehensive system to monitor, detect, and report all suspicious orders of opioids placed by pharmacies in the City of Huntington or Cabell County, West Virginia. This failure is exacerbated as there were significant timeframes when the Defendants would identify suspicious orders and still ship the orders to the respective pharmacies.

8. Cardinal Health, McKesson and AmerisourceBergen each failed to conduct adequate due diligence on suspicious orders of opioids placed by pharmacies in the City of Huntington or Cabell County, West Virginia, to determine whether the customer was engaged in diversion;

9. Cardinal Health, McKesson and AmerisourceBergen each distributed opioids to pharmacies in the City of Huntington, Cabell County, and the State of West Virginia in disproportionately excessive amounts without any documented justification; and

10. Cardinal Health, McKesson and AmerisourceBergen each failed to halt suspicious shipments of opioid orders to pharmacies in the City of Huntington and Cabell County they knew, or should have known, were going to be diverted.

III. STANDARDS

A. STATUTORY DUTY

Each distributor owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA

and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.[2]

The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.[3] Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.[4]

The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain ***illegal***.[5] "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."[6]

Distributors of Schedule II drugs—controlled substances with a "high potential for abuse"[7] – must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[8] The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[9] The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.[10]

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[2] *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

[3] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

[4] 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

[5] 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

[6] *United States v. Moore*, 423 U.S. 122, 135 (1975).

[7] 21 U.S.C. §§ 812(b), 812(2)(A)-(C)

[8] 21 U.S.C. § 823(b)(1).

[9] 1970 U.S.C.C.A.N. 4566, 4571-72.

[10] 1970 U.S.C.C.A.N. 4566, 4574.

Based on my review of all the relevant documents and testimony taken in this case[11] and MDL 2804 it is my opinion to a reasonable degree of professional certainty that the multiple distributors servicing Cabell County and Huntington, West Virginia, failed to maintain effective control against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1).

B. REGULATORY DUTY

Each distributor "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[12]

This regulatory duty has been defined to include the following obligations:

> The "***security requirement***" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the ***Reporting Requirement***). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out "potential illegal activity." *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the ***Shipping Requirement***).[13]

The regulatory duty is not difficult to follow and understand. An entity who voluntarily applies to become a registrant must submit an application and undergo a pre-registration investigation. The pre-registration investigation involves a thorough onsite inspection of the registrant's facilities as well as extensive instructions on the applicable regulations and the security requirements that must be followed. While there are numerous requirements related to registration, my opinions focus on the following compliance requirements:

- Maintain effective controls to prevent the diversion of controlled substances into "other than legitimate medical, scientific, and industrial channels";
- "Design and operate" a system to identify suspicious orders; and

[11] *City of Huntington v. AmerisourceBergen Drug Corporation, et al.*, Civil Action No. 3:17-01362, consolidated with *Cabell County Commission v. AmerisourceBergen Drug Corporation, et al.*, Civil Action No. 3:17-01665.

[12] 21 C.F.R. § 1301.74(b) [1971].

[13] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added).

- Report suspicious order "when discovered."

C. MDL2804 Discovery Ruling 12

The Court in MDL2804 issued a discovery ruling (Discovery Ruling 12) which outlines the statutory and regulatory duties imposed by federal law upon distributors of controlled substances.[14] The ruling addresses the following legal standards:

> Distributors of opioids are required to "'design and operate a system' to identify 'suspicious orders of controlled substances' and report those orders to DEA (the Reporting Requirement)." *Masters Pharmaceutical*, 861 F.3d 206, 212 (D.C. Cir. 2017) (quoting 21 C.F.R. § 1301.74(b)). Federal regulations explain that "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Thus, an order for opioids received by a distributor from a retail pharmacy may qualify as "suspicious" for any of a number of different reasons.[15]
>
> The simplest example is that a given order for an opioid may be suspicious if it was of "unusual size" – say, an order that pushed a pharmacy's monthly total number of opioid doses to exceed the monthly totals the same pharmacy had ordered in the prior six months. The Order refers below to this algorithm as the "Monthly Total Rule." (*Masters Pharmaceutical* described the "Monthly Total Rule" as follows: an order is suspicious if "that order—combined with other orders placed in the same

[14] *See* Discovery Ruling No. 12 regarding Suspicious Order Interrogatory [Doc. 1174].

[15] "Of course, an order may be suspicious for other reasons, even if it doesn't fit the Monthly Total Rule, such as that the pharmacy-customer "submitted more order forms in a 30-day period than it had in any of the prior six calendar months [the 'Order Form Rule'], or if the timing of the order did not comport with the customer's general ordering pattern over those six months [the 'Order Timing Rule']." *Id.* There are many other algorithms a distributor could use to identify opioid orders as suspicious, including: (1) the order for the opioid was placed within 30 days of an earlier suspicious order for the same opioid (the "Consecutive Order Rule"); (2) the order for the opioid was placed within 30 days of an order for the same opioid from a different distributor (the "Multi-Distributor Rule"); (3) the percentage increase in the amount of opioid ordered exceeded a certain threshold (the "Percentage Increase Rule"); or (4) the amount of opioid ordered exceeded by some threshold the amounts ordered by other similar or nearby pharmacies ("the Pharmacy Comparison Rule").

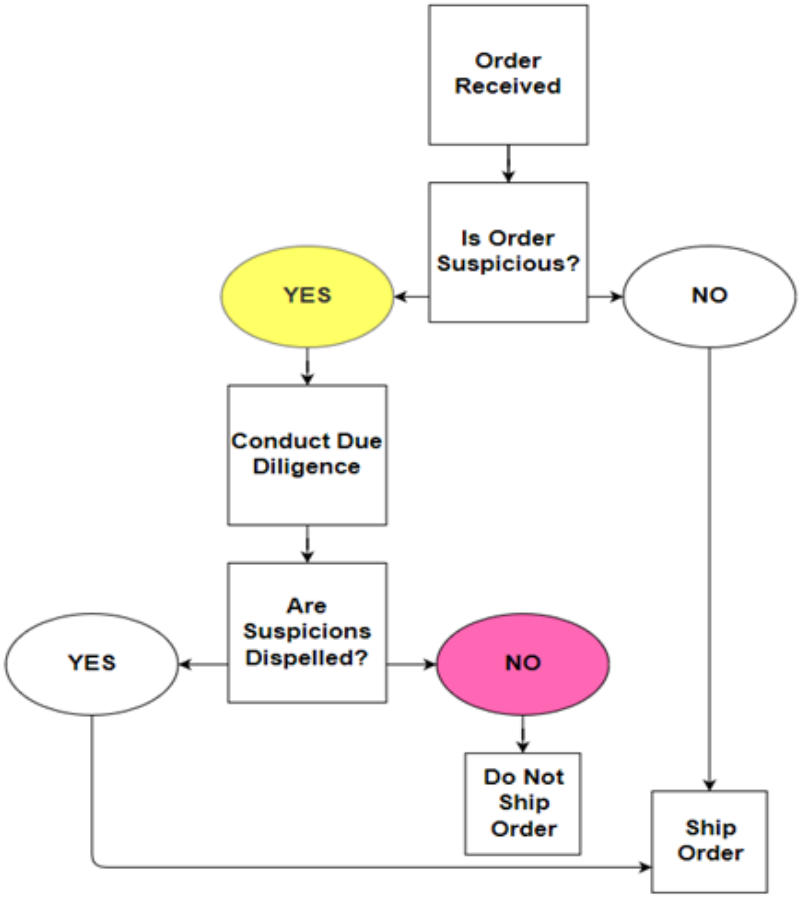
"*See also Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) ("a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy that engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious."); *id.* at *55478 (noting that "suspicion" is a low bar: it "is simply a far lower standard of proof than whether it is 'likely' that the circumstance exists," and "the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.")" Discovery Ruling No. 12, fn 2.

> 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months." *Id.* at 213.)
>
> As noted, once it has identified a suspicious order, a distributor is required to report it to the Drug Enforcement Agency ("DEA"). *See* 21 C.F.R. §1301.74(b) ("The [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [distributor]."). Furthermore, having received a suspicious order, the distributor "must make one of two choices: decline to ship the [suspicious] order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Id.* at 212–13. Of course, a distributor's due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed." *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) (hereinafter, "*Decision and Order*"). Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence." *Masters Pharmaceuticals*, 861 F.3d at 212.[16]

The Order noted the "legal authorities reviewed above leave unclear exactly when an order is deemed suspicious, and thus when a distributor is required to inform the DEA that it received a suspicious order. The following flowchart illustrates the issue."[17]

[16] Discovery Ruling No. 12 [Doc. 1174]. *See also, id.*, at n.3 ("The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.")

[17] *See* Discovery Ruling No. 12 issued December 9, 2018 at page 5.



This flowchart shows how a distributor's Suspicious Order Monitoring System must work and diagrams the process a distributor must undertake when it receives a suspicious order. Notably, there is a "yellow light" (caution) and a "red light" (stop) in the process. When a distributor first identifies an order as suspicious, this is a "yellow light" – it cannot ship the order without doing some investigation. If that investigation does not "dispel all red flags indicative that a customer is engaged in diversion," then the distributor gets a "red light" and must not ship the order. *Masters Pharmaceutical*, 861 F.3d at 222. Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done.

With regard to the Reporting Requirement, it is not entirely clear whether a distributor's obligation to inform the DEA attaches: (1) when the "yellow light"

flashes – that is, when the distributor first identifies an order as suspicious; or (2) only after the "red light" flashes – which would mean a distributor does not have to inform the DEA it received a suspicious order if investigation shows the order was legitimate, after all. Indeed, the authorities cited above provide support for each approach, as shown by the following quotations.

"Red Light"

- "[I]f, ***even after investigating the order***, there is any remaining basis to suspect that a customer is engaged in diversion; the order must be deemed suspicious and the Agency must be informed. *Decision and Order*, 80 Fed. Reg. at *55478.

- "DEA regulations expressly provide that deviations in size, frequency, or pattern are the sort of indicia that give rise to a suspicion and, ***unless the suspicion is dispelled***, the obligation to report. *Masters Pharmaceuticals*, 861 F.3d at 215 (citing *Decision and Order*, 80 Fed. Reg. at *55,479; and 21 C.F.R. §1301.74(b)).

"Yellow Light"

- "***Once a distributor has reported a suspicious order***, it must make one of two choices: decline to ship the order or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Masters Pharmaceutical*, 861 F.3d at 212–13.[18]

In other words, the Court determined it is unclear whether an order is "suspicious" (and so must be reported to the DEA) as soon as a distributor's SOMS flags it as suspicious, or only after due diligence fails to dispel any suspicion.[19] In any event, it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless they conduct "due diligence" that determines those orders are not likely to be diverted. Further, distributors are required to report suspicious orders to the DEA upon discovery.

[18] Discovery Ruling No. 12 [1174].

[19] The Court clarified in its *Ruling on Motion to Withdraw Portion of Discovery Ruling No. 12* [1189] that while Discovery Ruling No. 12 was "not a definitive pronouncement on [the Defendants'] legal obligations[,]" it was also not "in any way incorrect."

D. ARCOS/DADS

The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)[20] system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970[21] and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.[22]

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.[23]

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, among other things the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

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[20] "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, https://www.deadiversion.usdoj.gov/arcos/#background (last visited September 7, 2017).

[21] 21 U.S.C. 826(d).

[22] 69 FR 51104-02.

[23] *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

The ARCOS/DADS system uniquely has access to ***all*** of the data submitted by each DEA registrant from the across the country.[24] These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, inspection, investigations and other analyses.[25] Additionally, the DEA provides internet access to summary data from this system.

The DOJ/DEA disclosed the national ARCOS database to the Plaintiffs' Executive Committee (2006-2014) and additional transactional data was independently disclosed by some of the defendants. Both sets of data were then uploaded to a database managed by Craig J. McCann, PhD, CF, of Securities Litigation and Consulting Group, Inc. ("SLCG") (retained as an expert by the PEC). I have relied upon data derived from and provided by SLCG in the formulating of specific requests.

The ARCOS data, defendant transactional data, and the SLCG reports generated therefrom are consistent with the types of data, facts, information, and reports I would typically rely on in conducting the analysis and reaching the opinions contained herein. I am very familiar with the ARCOS data and defendant transactional data and have experience analyzing the data and reports generated therefrom. I have reviewed SLCG's methods and reports and they are consistent with my understanding, based on my experience, of how the data should be analyzed.

E. DEA DIVERSION INVESTIGATOR'S MANUAL.

The DEA published a manual which provides further guidance related to the statutory and regulatory duties of registrants. Portions of the manual have previously been publicly available and accurately set forth the charge for DEA investigators as follows:

> Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. ***The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled***

[24] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

[25] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html.

> ***substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.*** An investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.[26]

Importantly, the DEA does not approve or disapprove supplier shipments of controlled substances. The responsibility for making the decision to ship rests with the supplier.[27]

F. DEA DISTRIBUTOR INITIATIVE BRIEFINGS.

In August 2005, the DEA designed and implemented the DEA Distributor Initiative. The initiative was in response to the growing number of rogue Internet pharmacies illegally dispensing controlled substances and their pattern of purchasing extremely large amounts of a limited type of controlled substances from distributors. This program consisted of an individual meeting between the DEA and distributors to re-iterate to DEA registrants their responsibilities under the Controlled Substances Act and Code of Federal Regulations and to discuss current trends and methods of diversion.

In February 2014, at a conference in North Carolina, DEA Deputy Assistant Administrator Joseph T. Rannazzisi reported that the DEA had conducted distributor briefings to 81 registrants that had a total of 233 registered locations. The DEA has produced in discovery summaries of some of these meetings as follows:

- Memorandum, Meeting with Cardinal Health, Inc. Concerning Internet Pharmacies on August 22, 2005;[28]

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[26] *See* DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176914 at 01176957) ; *see also* DEA Diversion Manual (1990) (CAH_PRIORPROD_DEA_01176247 at 01176301); DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317 at 00953396, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("By its very nature, an order is a request to purchase controlled substances and has not yet been filled. Reporting a filled order is potentially allowing controlled substances to be diverted. Therefore, suspicious orders will not be filled.")

[27] See DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176247); see also DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("DEA field offices will not approve or disapprove a registrant's shipment of controlled substances, nor their procedures for detecting suspicious orders. The responsibility for detecting suspicious orders and making the decision to ship rests solely with the registrant.")

[28] US-DEA-00000352.

- Memorandum, Conference Call with. Mr. John. Gilbert of McKesson Corp. on November 28, 2005;[29]
- Memorandum, Meeting Between Office of Diversion Control (OD) and McKesson Corp. on January 3, 2006;[30]
- Memorandum, Internet Presentation; with AmerisourceBergen on August 10, 2005;[31] and
- Memorandum, Distributor Initiative Briefing with AmerisourceBergen Drug on May 16, 2017.[32]

At these briefings DEA personnel would reiterate the registrant's requirement to maintain effective controls to prevent diversion as required in U.S.C. 21 § 843(e) and 21 C.F.R. § 1301.71(a). During these meetings the DEA specifically focused on discussing 21 C.F.R. § 1301.74(b) which states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." DEA also advised the registrant at these meetings that DEA cannot tell a distributor if an order is legitimate or not.[33] The distributor has the responsibility to determine which orders are suspicious and, once identified, the distributor should report those orders to DEA and should not distribute suspicious orders.[34] Further, it was reiterated that a distributor was advised prior to shipping any order that had been determined to be suspicious, the distributor should conduct a due diligence investigation to ensure the controlled substances in the order are not likely to be diverted and document their due diligence actions.[35] Failure to do so could result in action against their DEA registration.

G. SEPTEMBER 2006 DEA GUIDANCE LETTER

In September 2006, in response to the nationwide growing health problems involving diversion of controlled substances, DEA Deputy Assistant Administrator Joseph T. Rannazzisi

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[29] US-DEA-00000369.

[30] US-DEA-00000371.

[31] US-DEA-00000147.

[32] US-DEA-00000144.

[33] US-DEA-00000352, 00000360.

[34] *Id.*

[35] *See also Novelty Distributors, Inc.,* 73 Fed. Reg. 52,689, 52,669 (Drug Enf't Admin. September 3, 2008) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.")

forwarded a letter to all DEA registered distributors and manufacturers.[36] The purpose of the letter was to reiterate the legal duties of distributors as DEA registrants and provide some examples of activities that may be indicative of diversion.

Mr. Rannazzisi's letter referenced 21 U.S.C. 823(e) that restated the requirement that distributors and manufacturers have a legal requirement to maintain effective controls against diversion. Mr. Rannazzisi's letter further cited DEA Regulation 21 C.F.R. 1301.74(b) which states the requirement for a registrant to design and operate a system to disclose suspicious orders of controlled substances and to report suspicious orders to the D.E.A. when discovered. The system should be capable of identifying a suspicious order based on size, pattern and frequency and of reporting that order to DEA. Contained in the written notification was a list of circumstances that may be indicative of diversion, which included the following:

a. Ordering excessive quantities of a limited variety of controlled substances.

b. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.

c. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.

d. Ordering the same controlled substances from multiple distributors.

The written communication also listed some guidance for a distributor by providing some possible inquiries of a customer's business activity that could be indicative of diversion. Mr. Rannazzisi further stated and reiterated:

> The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):
>
> > The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
>
> It bears emphasis that the foregoing ***reporting requirement is in addition to, and not in lieu of the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.***
>
> This, in addition to reporting all suspicious orders, ***a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels***. Failure to exercise such due diligence could, as circumstances warrant,

[36] *See* CAH_MDL_PRIORPROD_DEA07_00837645.

provide a statutory basis for revocation or suspension of a distributor's registration.[37]

H. JUNE 2007 SOUTHWOOD PHARMACEUTICALS, INC. DISTRIBUTOR CASE

DEA Deputy Administrator Michele M. Leonhart issued an Order on June 22, 2007[38], detailing the revocation of DEA registration for Southwood Pharmaceuticals, Inc ("Southwood"). The Order further denied any pending applications for renewal or modification of registration because of the imminent danger to the public health or safety.

The language contained in this Order clearly re-iterated the requirement for a distributor to have a suspicious order monitoring program. The Order states the following: "a registrant must 'design and operate a system to disclose to the registrant suspicious orders of controlled substances'"; suspicious orders must be reported to the local Field Division Office upon discovery by the registrant.[39] Under the regulation, suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.''

This Order also contains a description of the conduct of Southwood causing the revocation of their DEA registration as described in the Order to Show Cause and Immediate Suspension Order of Registration (OTSC/ISO) issued on November 30, 2006. The OTSC/ISO detailed that Southwood distributed controlled substances to customers they knew or should have known were diverting controlled substances. The OTSC/ISO stated Southwood repeatedly supplied excessive quantities of hydrocodone to fifteen pharmacies that were orders of unusual size and frequency as well as substantially deviating from the normal pattern. The OTSC/ISO further stated Southwood never reported any of the orders as suspicious to the DEA.

The OTSC/ISO also stated that Michael Mapes of the DEA conducted a meeting with Southwood by conference call on July 17, 2006. The content of the meeting described in the OTSC/ISO is consistent with the DEA Distributor Program being conducted by the DEA and described in this timeline. During this meeting Mr. Mapes discussed the purchasing activities of several pharmacies who were customers of Southwood. During this meeting Mr. Mapes also provided Southwood with a description of the illegal conduct of Internet pharmacies and described factors to consider when assessing customers for potential diversion. These factors included the size and frequency of order, range of product order, and the percentage of control substances ordered when compared to non-controlled substances. Mr. Mapes further discussed the factors that are required to ensure a prescription is legally prescribed by a physician.

The following statement is contained in the OTSC/ISO, "a pattern of drugs being distributed to pharmacies [which] are diverting controlled substances demonstrates a lack of effective controls against diversion by the distributor" and could lead to the revocation of the distributor's registration." Mr. Mapes further stated, "… any distributor who was selling controlled

[37] *See id.* (emphasis added).

[38] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007).

[39] 21 CFR 1301.74(b).

substances that are being dispensed outside the course of professional practice must stop that distribution immediately."[40]

The OTSC/ISO stated Mr. Mapes discussed with Southwood representatives whether it could ship an order which it had reported as suspicious. Mr. Mapes advised Southwood representatives if they reported a suspicious order to the DEA, they still needed to make the decision as to whether to ship the order. The OTSC/ISO further detailed that Southwood representatives asked Mr. Mapes whether they should stop shipping controlled substances to the internet pharmacies and Mr. Mapes replied the DEA cannot tell a distributor whether a particular order is legitimate, and that the decision of whether to ship was "a business decision," but Southwood had an obligation to ensure that the controlled substance being distributed were used for legitimate medical purposes.

I. DECEMBER 2007 DEA GUIDANCE LETTER

In December 2007, DEA Deputy Assistant Administrator for the Office of Diversion Control Joseph T. Rannazzisi issued a second letter to all DEA registered distributors and manufacturers restating much of the information contained in the previous letter.[41]

This letter was focused on reiterating the responsibilities of manufacturers and distributors to inform DEA of suspicious orders as required by 21 CFR 1301.74(b).

The letter reiterated that 21 CFR 1301.74(b) requires a manufacturer or distributor to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The letter further notified registrants that it is the sole responsibility of registrants to design and operate the system. The letter advised registrants of the following: "Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for report suspicious orders, should no longer be taken to mean that DEA approves a specific system."[42]

The letter also notifies that filing a monthly report of transactions to the DEA, often referred to as excessive purchase reports, does not meet the regulatory requirement to report suspicious orders.

The letter also reiterated the following requirements:

1. 21 CFR 1301.74(b) requires DEA registrants inform the DEA of suspicious orders when discovered by the registrant.

2. DEA registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine if the controlled substances are likely to be diverted.

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[40] *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487, 36,492(Drug Enf't Admin. July 3, 2007).

[41] CAH_MDL_PRIORPROD_DEA07_00092296.

[42] *Id*.

3. The regulation states suspicious orders include orders of an unusual size, deviating substantially from a normal pattern, and orders of an unusual frequency. The criteria are disjunctive and are not all inclusive.

4. DEA registrants who routinely report suspicious orders, yet fill these orders without first determining whether the orders are not being diverted may be failing to maintain effective controls against diversion that may result in possible action against their DEA registration.

J. DEA ADMINISTRATIVE ACTIONS

Distributors in this industry regularly monitor DEA administrative actions involving maintenance of effective controls against diversion and failure to identify and/or report suspicious orders. There are many different types of sources that make the details of DEA administrative action available for the industry to review. The type of information available can be a very in-depth article or a publication as simple as a press release. Two examples of in-depth sources of information are the information published in the Federal Register involving DEA cases against Masters Pharmaceutical Inc. and Southwood Pharmaceuticals Inc.

The DEA posts administrative case information on the Internet on their website at www.deadiversion.usdoj.gov. The DEA and Department of Justice also normally issue press releases on administrative actions that subsequently generate media coverage and reviews by law firms. Further, trade organizations like the Healthcare Distribution Alliance (HDA) typically publish articles regarding DEA administrative actions for review by their members. Typically, when a DEA administrative action occurs, several of the law firms that closely follow the industry, post articles on their websites that describe the action and offer opinions of future impact to the industry.

Listed below are some of the significant administrative action against distributors and manufacturers for failing to maintain effective controls against diversion and for failing to identify and/or reports suspicious orders:

1. April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency.[43]

[43] AmerisourceBergen Corporation, *AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of its Orlando Distribution Center's Suspended License to Distribute Controlled Substances*, June 22, 2007, available at https://investor.amerisourcebergen.com/news/news-details/2007/AmerisourceBergen-Signs-Agreement-with-DEA-Leading-to-Reinstatement-of-Its-Orlando-Distribution-Centers-Suspended-License-to-Distribute-Controlled-Substances/default.aspx (last visited August 3, 2020).

2. June 22, 2007, the DEA revoked the Registration of Southwood Pharmaceuticals, Inc. 72 Fed. Reg. 36,487 (Department of Justice; Southwood Pharmaceuticals, Inc.; Revocation of Suspension (July 2, 2007)) on Tuesday, July 3, 2007July 3, 2007, Department of Justice, Drug Enforcement Administration article in the Federal Register, titled, Southwood Pharmaceuticals, Inc.; Revocation of Registration.[44]

3. November 29, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center which suspended their DEA registration for failure to maintain effective controls against diversion of hydrocodone.[45]

4. December 7, 2007, DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[46]

5. December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[47]

6. January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone. Cardinal agreed to suspend shipping any controlled substances from the location pending a resolution with the DEA.[48]

7. May 2, 2008, McKesson Corporation agree to pay a $13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would

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[44] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007)(*also available at* https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm (last visited March 10, 2019)).

[45] Cardinal Health, Press Release, *Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility*, November 29, 2007, available at https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx (last visited March 11, 2019).

[46] Cardinal Health, Press Release, *Cardinal Health to Cease Distribution of Controlled Substances from Florida Facility*, December 7, 2007, available at https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122500 (last visited August 3, 2020).

[47] Drug Topics, "DEA hits third Cardinal Health distribution center," December 21, 2007, available at https://www.drugtopics.com/pharmacy/dea-hits-third-cardinal-health-distribution-center (last visited August 3, 2020).

[48] Drug Topics, "Cardinal caught between DEA and pharmacies over diversion control," April 14, 2008, available at https://www.drugtopics.com/community-practice/cardinal-caught-between-dea-and-pharmacies-over-diversion-control (last visited August 3, 2020).

"maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."[49]

8. On September 30, 2008, Cardinal Health agreed to pay a $34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances.[50]

9. January 9, 2009, Rite Aid agreed to pay $5 Million in civil penalties to resolve allegations that Rite Aid knowingly filled prescriptions for controlled substances that were not issued for legitimate medical purposes; failed to notify the DEA of significant thefts and losses of controlled substances; failed to maintain or failed to furnish to the DEA upon request records required to be kept under the Controlled Substances Act for a period of two years; and failed to properly execute DEA forms used to ensure the amount of Schedule II drugs ordered by Rite Aid were actually received violations of the Controlled Substances Act in eight states.[51]

10. April 21, 2009, Settlement and Release Agreement and Administrative Memorandum of Agreement between DOJ/DEA and Masters Pharmaceutical Inc.[52]

[49] Settlement and Release Agreement and Administrative Memorandum of Agreement, entered into May 2, 2008, between DEA and McKesson Corporation, available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf (last visited August 3, 2020).

[50] United States Attorney's Office. (October 2, 2008) *Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html (last visited August 3, 2020).

[51] United States Department of Justice, (January 12, 2009) *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations (last visited August 3, 2020).

[52] Settlement and Release Agreement and Administrative Memorandum of Agreement between DEA and Masters Pharmaceutical, Inc. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Masters%20Pharmaceutical%20-%202009.pdf (last visited August 3, 2020).

11. June 15, 2010, Order to Show Cause – Immediate Suspension Order served to The Harvard Drug Group, Livonia, MI.[53]

12. June 10, 2010, DEA suspended Sunrise Wholesale, Inc. from selling controlled substances for supplying excessive amounts of oxycodone to "pill mills."[54]

13. October 13, 2010, settlement was reached between the DEA and CVS Pharmacy, Inc. resolving the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy distribution center in Southern California. CVS paid a penalty of $75,000,000.00 and forfeited $2.6 million in profits for a total payment of $77.6 million.[55]

14. April 18, 2011, Harvard Drug Group agreed to pay $8,000,000 in civil penalties as part of settlement with DEA related to allegations that Harvard failed to have in place an effective system for identifying suspicious orders of controlled substances, violating the Controlled Substances Act.[56]

15. June 10, 2011, Order to Show Cause and Immediate Suspension Order served on Keysource Medical Inc. Keysource Medical distributed 48 million doses of oxycodone products to Florida Pharmacies.[57]

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[53] Administrative Memorandum of Agreement between DEA and The Harvard Drug Group, LLC dated March 28, 2011. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Harvard%20Drug%20Group%20-%202011.pdf (last visited August 3, 2020).

[54] LaMendola, Bob. "DEA accuses Sunrise company of supplying painkillers to 'pill mills.'" Sun-Sentinel. June 22, 2010. Available at https://www.sun-sentinel.com/business/fl-xpm-2010-06-22-fl-drug-wholesaler-stopped-20100621-story.html (last visited August 3, 2020).

[55] United States Attorney's Office. (October 14, 2010) *CVS Admits Illegally Selling Pseudoephedrine to Criminals who made Methamphetamine, Agrees to Pay $77.6 Million to Resolve Government Investigation* [Press Release]. Available at https://www.justice.gov/archive/usao/cac/Pressroom/pr2010/148.html (last visited August 3, 2020).

[56] United States Drug Enforcement Administration. (April 18, 2011) *Michigan Based Pharmaceutical Wholesaler Harvard Drug Group to Pay $8,000,000 in Settlement* [Press Release]. Available at https://www.dea.gov/press-releases/2011/04/18/michigan-based-pharmaceutical-wholesaler-harvard-drug-group-pay-us (last viewed on August 3, 2020).

[57] United States Drug Enforcement Administration. (June 10, 2011) *Cincinnati Pharmaceutical Supplier's DEA License Suspended* [Press Release]. Available at https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended (last visited August 3, 2020).

16. July 6, 2011, Order Denying Plaintiff's (Keysource Medical) Motion for Temporary Restraining Order and for Preliminary Injunction.[58]

17. February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone.[59]

18. March 7, 2012, Memorandum of Opinion [Doc. 32] from the United States District Court for the District of Columbia, *Cardinal Health, Inc., vs. Eric H. Holder, Jr.*, Civil Action No. 12-185 (RBW), denying Cardinal's challenge of the DEA's Order to Show Cause and Immediate Suspension of Registration of Cardinal's Lakeland Distribution Center.[60]

19. April 5, 2012, A United States Attorney Office press release stated Keysource Medical agreed to pay a $320,000 fine for failing to guard against diversion of controlled substances. and states Keysource Medical agreed to voluntarily surrender its DEA registration in September 2011.[61]

20. May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA was inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years.[62]

21. March 28, 2013, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc and Oklahoma CVS Pharmacy, L.L.C., to resolve claims that CVS violated the CSA by: (1) filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS

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[58] *Keysource Medical, Inc., v. Attorney General of the United States, et al.*, No. 1:2011cv00393, *Order Denying Plaintiff's Motion for Temporary Restraining Order and for Preliminary Injunction* [Doc. 22], available at https://law.justia.com/cases/federal/district-courts/ohio/ohsdce/1:2011cv00393/147299/22/ (last visited August 3, 2020).

[59] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[60] Copy of Order available at https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf (last visited August 3, 2020).

[61] United States District Attorney's Office, Southern District of Ohio. (April 5, 2012) *Cincinnati Pharmaceutical Distributor to Pay $320,000 for Failing to Guard Against Diversion of Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/ohs/news/04-05-12.html (last visited August 3, 2020).

[62] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

dispensing records including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions. CVS paid a fine of $11,000,000.00.[63]

22. In July, 2013, the DEA initiated a regulatory investigation at CVS Indiana. After the investigation and after the DEA had informally indicated its displeasure with what it found at CVS, Mark NiCastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. In the correspondence, Mr. NiCastro attempted to explain to the DEA why the CVS Indiana distribution center had never reported a suspicious order and he wrote:

> "In your recent email, you asked for information concerning CVS store orders that have been stopped outside of Indiana. Across the chain, the CVS SOM process has stopped and cancelled orders. I have attached the dates and the offices to which we reported these orders. As we discussed during the DEA audit and during our recent phone call, it is important to remember that CVS is shipping only to its own stores, and there are additional due diligence processes in our pharmacy operations group which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores. This is a primary contributor to the limited number of suspicious orders identified through our distributor SOM process."[64]

23. July 17, 2013, Walgreens agreed to pay $80 Million in civil penalties related to allegations that Walgreens was filling numerous prescriptions that Walgreens employees knew, or should have known, were not issued for a legitimate medical purpose.[65]

24. June 19, 2014, In Regards to Masters Pharmaceutical the Administrative Law Judge issued a Recommended Decision in regards to the Order to Show Cause Hearing that occurred on February 24 through 28 and March 3 through 4, 2014. [66]

25. On September 2, 2014, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The settlement resolved claims against CVS for filling from April 1, 2012 to July 31, 2012, 153 prescriptions at eight different pharmacies, written by Dr.

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[63] CVS-MDLT1-000060822 – 000060829.

[64] *See* NiCastro Depo. at 204-207; Ex. 42.

[65] United States Attorney's Office, Eastern District of New York. (July 17, 2013) *Eastern District U.S. Attorney's Office Participates in Record Settlement: Walgreens Agrees to Pay $80 Million in Civil Penalties Under the Controlled Substnaces Act* [Press Release]. Available at https://www.justice.gov/usao-edny/pr/eastern-district-us-attorney-s-office-participates-record-settlement-walgreens-agrees (last visited August 3, 2020).

[66] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

Pedro Garcia during a time period for which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a $1,912,500 fine.[67]

26. On May 12, 2015, a settlement was reached among the United States and the DEA and CVS Health and all of its subsidiaries and affiliates. The settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64." The Settlement also covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances into other than21 U.S.C. §823(e)" and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of $22,000,000.00.[68]

27. On July 24, 2015, a settlement was reached among the United States and the DEA and CVS Health to resolves claims that from May 1, 2013 through July 30, 2014, CVS failed to keep complete and accurate records of Schedule II controlled substances at a CVS store in Massachusetts in violation of 21 U.S.C. § 827(a)(3) and 21 C.F.R. §§ 1304.11(e)(3)(i), 1304.21, and 1304.22; and that CVS failed to report a March 14, 2014 robbery to the DEA within one business day in violation 21 C.F.R. § 1301.76(b). CVS paid a $50,000 fine.[69]

28. On August 7, 2015, a settlement was reached among the United States, the DEA and CVS Health. The settlement resolved claims that between March 3, 2010 and August, 2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA number ("knew or should have known" in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a $450,000 fine.[70]

29. September 8, 2015, Masters Pharmaceutical – DEA Acting Administrator Chuck Rosenberg issued a Final Order revoking the DEA registration of Master Pharmaceutical Inc.[71]

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[67] CVS-MDLT1-00060907–000060914.

[68] CVS-MDLT1-000060796–000060804.

[69] CVS-MDLT1-000099702–000099704.

[70] CVS-MDLT1-000060847–000060855.

[71] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

30. On December 18, 2015, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The settlement was the result of a DEA Inspection that was performed after CVS reported the theft of over 40,000 dosages of controlled substances by two former employees from a Texas CVS pharmacy. The inspection that was started due to theft demonstrated that CVS again failed its CSA obligations. CVS paid a fine of $345,000.00.[72]

31. On December 31, 2015, the DEA issued a letter of admonishment for violations in distributing hydrocodone combination products (HCPs) at the CVS Indiana distribution center. This DEA finding was the result of the July 2013 investigation. Before the admonishment, Agent Gillen of the DEA sent an email to Mr. Nicastro outlining that CVS Store No. 6880 ordered 1,888,600 dosage units of hydrocodone between January 1, 2012 and October of 2013. The pharmacy is located in Vincennes, IN with a population of approximately 18,000 people. Additionally, he indicated that Store No. 6757 ordered 2,012,400 of hydrocodone tablets for Columbus, IN, which has a population of 45,000. Agent Gillen then writes: "Both stores have purchased a large quantity of Hydrocodone given their population."[73]

32. On February 12, 2016, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. In the settlement, CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA…" CVS paid a fine of $8,000,000.00.[74]

33. June 30, 2016, CVS agreed to pay $3.5 Million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.[75]

34. On October 20, 2016, a settlement was reached among the United States and CVS Pharmacy, Inc. The settlement resolved claims from an investigation that the DEA began in January 2016. The DEA investigated two CVS stores in Connecticut. Although the offending conduct occurred after CVS quit distributing HCPs, it is indicative of the overall pattern and practice of CVS. The settlement resolved claims that CVS failed to keep paper

[72] CVS-MDLT1-00060915-00060921.

[73] *See* CVS-MDLT1-00008014-00008015; CVS-MDLT1-000076135.

[74] CVS-MDLT1-000060805-00060811.

[75] United States District Attorney's Office, District of Massachusetts. (June 30, 2016) *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions* [Press Release]. Available at https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions (last visited August 3, 2020).

Schedule III-V prescriptions either in a separate prescription file or readily retrievable from other prescription records, which allegedly violated 21 U.S.C. 827(b)(2)(A) and (B) and 21 C.F.R. 1304.04(h)(4) and failed to keep Schedule III-V purchase invoices on at least 31 occasions in separate or in a readily retrievable manner from all other records of the pharmacy, which allegedly violated 21 U.S.C. 827(b)(2)(A) AND (b) AND 21 C.F.R. 1304.04(h)(3). CVS paid a $600,000 fine.[76]

35. December 22, 2016, Consent Order entered into between the United States and Kinray, LLC, a subsidiary of Cardinal Health.[77]

36. December 23, 2016, Cardinal Health agreed to pay a $34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligation under the CSA in Florida, Maryland, New York, and Washington.[78]

37. January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.[79]

38. January 18, 2017, Walgreens agreed to pay $200,000 following an investigation by the Massachusetts Attorney General's Office, which found that Walgreens failed to track the opioid use of high-risk patients in the state's Medicaid program.[80]

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[76] CVS-MDLT1 000060830 – 000060838.

[77] *United States of America v. Kinray, LLC*, Case #16 Civ. 8767-RA. Available at https://www.justice.gov/usao-sdny/press-release/file/920806/download (last visited August 3, 2020).

[78] United States Attorney's Office, Middle District of Florida. (December 23, 2016) *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under (last visited August 3, 2020).

[79] United States Department of Justice. (January 17, 2017) *McKesson Agrees to Pay record $150 Million settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* [Press Release]. Available at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (last visited August 3, 2020).

[80] Associated Press, "Walgreens to pay $200k, change opioid procedures," The Washington Times, January 19, 2017, available at https://www.washingtontimes.com/news/2017/jan/19/walgreens-to-pay-200k-change-opioid-procedures/) (last visited August 3, 2020).

39. March 9, 2017, Rite Aid paid $834,200 to the United States to settle claims that Rite Aid pharmacies in Los Angeles, California dispensed and/or recorded controlled substances using a medical practitioner's incorrect or invalid DEA registration number.[81]

40. June 30, 2017, the United States Court of Appeals for the District of Columbia Circuit published an opinion denying Masters Pharmaceutical's petition of review and upholding the Final Order.[82]

41. On July 5, 2017, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The settlement was the result of an investigation began by the DEA as a result of "an increase in the number of thefts and explained losses of Hydrocodone…" at numerous Eastern District of California CVS retail stores. The settlement resolved claims for the following misconduct: 1) failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances (*see* 21 C.F.R. §1301.71(a)) and failure to notify DEA of certain thefts or significant losses of controlled substances within one business day of the discovery (*see* 21 C.F.R. §1301.74(c)); 2) failure to maintain schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms (21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their recordkeeping obligations, but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of $5,000,000.00.[83]

42. July 7, 2017, the Department of Justice/DEA and Mallinckrodt entered into a Memorandum of Agreement to resolve allegations that Mallinckrodt failed to maintain effective controls to prevent diversion and to detect and report suspicious orders.[84]

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[81] United States Attorney's Office, Central District of California. (March 9, 2017) *Rite Aid Corporation Pays $834,300 to Settle Allegations of Violating the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-cdca/pr/rite-aid-corporation-pays-834200-settle-allegations-violating-controlled-substances-act (last visited August 3, 2020).

[82] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

[83] CVS-MDLT1 000060856-000060871.

[84] Administrative Memorandum of Agreement between DEA and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, dated July 7, 2017. Available at https://www.justice.gov/usao-edmi/press-release/file/986026/download (August 3, 2020).

43. January 24, 2018, the U.S. Attorney's Office entered into a settlement with Rite Aid for improper sales of the meth precursor pseudoephedrine.[85]

44. On June 15, 2018, a settlement was reached among the United States, the DEA and CVS Health. The settlement resolved claims that between February, 2013 and January, 2015, CVS failed to report to the DEA in writing, within one business day of discovery, thefts or significant losses of controlled substances, including hydrocodone, from certain Long Island CVS Pharmacy retail stores, as required by 21 C.F.R. §1301.76(b). CVS agreed to pay a $1,500,000.00 fine. (CVS-MDLT1-000060839 – 000060846).

45. On July 29, 2018, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc., to resolve claims related to a November 2013 inspection of a CVS Pharmacy in Calera, Alabama. The settlement resolved claims that CVS violated the CSA, as a result of violations of : (1) 21 C.F.R. 1305.13(c) (requirement to record the amount received and/or the date received on DEA 222 forms); (2) 21 C.F.R. 1304.21(a) (requirement to maintain complete and accurate records); and (3) 21 C.F.R. 1304.21(a) and/or (d) (requirement to document the number of packages received or the date package received on Schedule III through V purchase invoices). CVS agreed to pay a $1,000,000 fine.[86]

46. August 21, 2018, CVS agreed to pay $1 Million to settle allegations that CVS stores in Alabama failed to keep adequate records in violation of the Controlled Substances Act.[87]

47. December 31, 2018, the DEA and the Rhode Island Attorney General announced a $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums.[88]

K. INDUSTRY GUIDELINES - HEALTHCARE DISTRIBUTION ALLIANCE

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[85] United States Attorney's Office, Southern District of West Virginia. (January 24, 2018) *U.S. Attorney's Office enters settlement with Rite Aid based on improper sales of meth precursor pseudoephedrine* [Press Release]. Available at https://www.justice.gov/usao-sdwv/pr/us-attorneys-office-enters-settlement-rite-aid-based-improper-sales-meth-precursor (last visited August 3, 2020).

[86] CVS-MDLT1-000060812 –000060821.

[87] United States Attorney's Office, Northern District of Alabama. (August 21, 2018) *CVS Pharmacy Pays $1 Million Penalty in Settlement with DOJ for Violations of the Controlled Substances* [Press Release]. Available at https://www.justice.gov/usao-ndal/pr/cvs-pharmacy-pays-1-million-penalty-settlement-doj-violations-controlled-substances-act (last visited August 3, 2020)

[88] United States Drug Enforcement Administration. (December 31, 2018) *DEA and Attorney General Kilmartin announces $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums* [Press Release]. Available at https://www.dea.gov/press-releases/2018/12/31/dea-and-attorney-general-kilmartin-announces-300000-settlement-rite-aid (last visited August 3, 2020).

A large number of drug distributors and manufacturers are members of The Healthcare Distribution Alliance (HDA), a trade organization that provides industry information, as well as guidance on best practices, industry standards, regulation/legal changes, and other related services.

A review of the website for The Healthcare Distribution Alliance (HDA) provided the following history of the organization.[89] The Western Wholesale Druggists' Association (WWDA) was formed on March 15, 1876 and consisted of 95 wholesale druggists. In 1882 the WWDA became the National Wholesale Druggists Association (NWDA) that was representing distribution companies as an advocate in the distribution industry.

In 2000 the NWDA organization was renamed the Healthcare Distribution Management Association (HDMA). The website stated the organization's name change reflected the "Association's vision of a progressively more efficient and effective distribution system." In 2016 the HDMA changed names to the Healthcare Distribution Alliance (HDA). The website states the following, "Now headquartered in Arlington, Virginia, HDA represents 36 distribution companies — national, regional and specialty — as well as more than 130 manufacturer and more than 50 service provider/international members, respectively. These members serve more than 200,000 licensed healthcare providers, delivering over 15 million lifesaving products to these outlets every day. But just as in 1876, HDA's mission has remained the same, which is to protect patient safety and access to medicines through safe and efficient distribution; advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and, create and exchange industry knowledge and best practices."

1. *NWDA 1984 Suspicious Order Monitoring Policy*

A review of Cardinal Health discovery material revealed a thirty-eight page document from 1984 by NWDA which was a draft outline of a suspicious order monitoring system. The documents can be found in the Cardinal Health discovery material in a group of documents that begin with a cover page containing, "NWDA Suspicious Order Monitoring System" with this stamped information, "Received Jun 21 1993 by Folsom."[90]

The first seven pages of the document describes some of the elements of a suspicious order monitoring system. These seven pages do not contain a date indicating when the system was designed. There are two DEA letters in the documents that do identify a date. These DEA letters provide comment and guidance to NWDA in regards to the suspicious order monitoring system. The first DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA), and signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA). The letter contained a stamped date of April 27, 1984, which details a meeting between the two on April 13, 1984. This letter stated the DEA reviewed a draft form of the suspicious order monitoring system. This DEA letter contained the following comment:

[89] *See* https://www.hda.org/ (last viewed on August 3, 2020).

[90] The group of documents described in this section can be found in the Cardinal Health discovery material with a Bates stamp range of CAH_MDL2804_01465723 to CAH_MDL2804_01465761.

> The NWDA's draft format for a suspicious order monitoring system provides an excellent framework for distributor registrants to "…design and operate a system to disclose to the registrant suspicious orders of controlled substances." (21 CFR 1301.74(b).) However, I am compelled to note, as I have in our previous discussions, that any automated data compliance processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler. As previously discussed, an after-the-fact computer printout of the sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered. I am enclosing a copy of your draft with my pen-and-ink changes."[91]

The second DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA), signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA) that was stamped with a date of May 14, 1984, which appeared to be a follow-up communication from the April 27, 1984 letter. This letter details that there was an NWDA meeting that was attended by DEA employee David Walkup. This DEA letter contained the following comment:

> I want to assure you that DEA fully supports NWDA's effort to introduce a uniform reporting system among its members. This system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b). However, I want to make it clear that the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders. DEA has interpreted "orders" to mean prior to a shipment.[92]

The background section of the system details it was created in co-operation with the DEA. Further, the document states that the DEA may be providing some variances and limits that would be incorporated into the suspicious order monitoring system.

On page 7 of the suspicious order monitoring system document is "Section IX" that contains the following statement: "Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of report these excessive or suspicious orders. DEA has interpreted 'orders' to mean prior to a shipment." This statement along with the letter from DEA is an important communication that shows that the DEA was requiring the suspicious order monitoring system to identify single orders of controlled substances that must be reported immediately, prior to being shipped.

2. *2008 Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances.*

[91] CAH_MDL2804_01465723, 01465732.

[92] CAH_MDL2804_01465723, 01465734.

In 2008, the HDMA posted on their website industry compliance guidelines that were titled, "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances." The introduction of the document contained this comment:

> At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support security of controlled substances they deliver to their customers. Due Diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.[93]

On October 17, 2008, DEA Chief Counsel Attorney Wendy H. Goggins sent a written statement to HDMA President and CEO John M. Gray commending the HDMA for their efforts to assist their members in fulfilling the obligations regarding the Controlled Substance Act and corresponding regulations.[94]

The HDMA compliance guidelines document contains a general framework for a basic suspicious order monitoring system.[95] The document contains the following elements with accompanying suggested guidelines:

1. Know Your Customer Due Diligence
2. Monitoring for Suspicious Orders
3. Suspend/Stop an Order of Interest Shipment
4. Investigation of Orders of Interest
5. File Suspicious Order of Interest
6. Employees, Training and Standard Operating Procedures (SOPs)
7. Additional Recommendations
8. Glossary of Abbreviations

Although there are several areas or concerns which might render a suspicious order monitoring system less effective, the guidance provided by HDMA does contain several elements that are consistent with compliance with 21 C.F.R. Section 1301.71(a) and 1301.74(b). Some of the areas of guidance are the following:

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[93] February 10, 2012 Declaration of Joseph Rannazzisi, CAH_MDL_PRIORPROD_DEA12_00014479, 00014512.

[94] CAH_MDL_PRIORPROD_DEA12_00000825.

[95] CAH_MDL_PRIORPROD_DEA12_00000826.

1. Recommending distributors conduct thorough due diligence investigations that are documented and retained is essential in establishing a customer and providing a history for any further compliance actions or investigations.[96]

2. Providing guidance for a distributor to develop an electronic suspicious order system as detailed in a standard operation procedure, although not required by regulation, demonstrates HDMA recognizes the manual review of orders for deviations in size, frequency, or pattern would render it ineffective.[97]

3. Separating customers by business activity or class of trade is an essential system element. Further enhancement for monitoring and setting averages would be to form subgroups by the size of the customer.[98]

4. Recommending of placing the controlled substances being monitored into groups or families provides a starting point for setting an average and monitoring. Only monitoring drug families and failing to evaluate the unusual order size, pattern, or frequency of any specific drug within a drug family has a much higher probability of failing to identify diversion of specific highly abused drugs.[99]

5. Thresholds may be set by using averages shipped to a customer's facility that are consistent with that class of customer. Threshold are recommended to be calculated for single orders and average monthly orders per family, per customer, and class of trade. Thresholds should utilize the information obtained in the due diligence investigation. A sales history of a minimum of six months and a maximum of 24 months is recommended. Thresholds for new customer accounts should be established at the lowest level indicated by the due diligence investigation. An important component is the periodic review of cumulative orders for the customer to evaluate purchasing trends. [100] Note: The use of a six-month average does not provide a sufficient purchase history for establishing accurate thresholds.

6. A distributor should consider allowing use of alternative criteria, outside of the suspicious order system, to be utilized to identify a suspicious order.[101]

7. On page 9, Section III in the section titled, SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT, there is clear guidance from HDMA of what action should be taken by a distributor when an order exceeds a threshold which is contained in the following statement, "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise

[96] CAH_MDL_PRIORPROD_DEA12_00000826, 00000829-00000832.

[97] CAH_MDL_PRIORPROD_DEA12_00000826, 00000832.

[98] CAH_MDL_PRIORPROD_DEA12_00000826, 00000833.

[99] *Id.*

[100] *Id.*

[101] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000834.

characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[102]

8. Recommending that if an order meets or exceeds a threshold the distributor examine the order further. The examination aids the distributor in deciding to either fill the order and ship or to continue to hold the order. This section also states, "Further examination will also aid in determining whether the and when to report the order to DEA under 21 C.F.R. Section 1301.74(b)."[103]

9. The following statement is made in regard to an order of interest, "The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest."[104]

12. A customer interview should be conducted in regards to order. Any information provided by the customer should be verified and documented.[105]

13. All investigation conducted by the distributor should be "fully documented," and all records retained in an appropriate section. A critical element of guidance states the following, "The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." The statement should be signed and dated by the reviewer."[106]

15. An order determined to be "suspicious" should be reported immediately upon being so determined.[107]

18. The following guidance was provided for the content of the standard operating policy:

    a. Describe how an initial review and investigation will be conducted;

    b. Reflect the distributor's and its customers' business conditions;

    c. Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;

[102] *Id.*

[103] *Id.*

[104] *Id.*

[105] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000835.

[106] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000836.

[107] *Id.*

d. Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";

e. Define a process for reporting to DEA under 21 C.F.R. Section 1301.74(b); and

f. Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.[108]

19. If a distributor concludes an order is suspicious after conducting an investigation it is recommended the distributor make a determination whether it will subject future orders from the same customer for the same drug product to more rigorous scrutiny and/or consider whether to cease filling all future orders of that drug product or all controlled substances.[109]

L. DEA CHEMICAL HANDLERS MANUAL

Cardinal Health (and others) have responded to discovery referencing the DEA's Chemical Handlers Manual and/or the 1998 Reno Report as "guidance" provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including prescription opiates.[110] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[111]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

M. U.S. HOUSE OF REPRESENTATIVES INVESTIGATION INTO OPIOID DISTRIBUTIONS IN WEST VIRGINIA

[108] *Id.* at CAH_MDL_PRIORPROD_DEA12_00000826, 00000837.

[109] *Id.*

[110] *See, e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[111] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

In May 2017, the United States House of Representatives, Energy and Commerce Committee (E&C Committee), opened an investigation into allegations that large amounts of opioids were shipped by wholesale drug distributors to small-town pharmacies located in southwestern West Virginia over the last decade. The purpose of the investigation was to determine whether wholesale distributors played a role in the opioid crisis in West Virginia, "part of the epicenter of the nation's opioid epidemic and the state with the highest drug overdose death rate in the country,"[112] and to examine the efforts of the Drug Enforcement Administration's response to the crisis. In December 2018, the E&C Committee published a report of their findings in a document titled, "Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia."

A major portion the E&C Committee report is spent detailing the conduct of the following five (5) wholesale distributors who were distributing opioids to pharmacies in West Virginia:

a. AmerisourceBergen Drug Company
b. Cardinal Health, Inc.
c. McKesson Corporation
d. H.D. Smith Wholesale Drug Company
e. Miami Luken, Inc.

The E&C Committee report detailed its investigation into wholesale distributors' due diligence efforts, use of drug thresholds, suspicious order reporting, and shipping opioids to pharmacies despite the presence of red flags of diversion. The E&C Committee utilized company records and statements by company representatives to review each company's due diligence efforts, which are essential in maintaining effective controls to prevent the diversion of controlled substances. The E&C Committee provided the following statement summarizing its findings:

> "Despite these processes and procedures, documents obtained during the Committee's investigation showed, by large, a cursory due diligence process.
>
> The documents also showed little evidence that distributors considered, or requested additional explanation, when provided with information during the diligence process that should have raised a red flag. The Committee found instances where wholesale distributors established, or in some case, reestablished business relationships with questionable pharmacies despite the presence of multiple red flags."[113]

[112] United States, Congress, House, Committee on Energy and Commerce. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, p. 4 (available at https://republicans-energycommerce.house.gov/wp-content/uploads/2018/12/Opioid-Distribution-Report-FinalREV.pdf) (last visited August 3, 2020).

[113] *Id*. at p. 124.

The Committee's findings regarding the distributors' failures to adequately conduct and document due diligence efforts, are consistent with my own review of the documents, testimony, and due diligence files produced in this litigation by Cardinal, McKesson, and AmerisourceBergen.

Additionally, the Committee's findings with respect to the defendants' distributions to pharmacies in Southwestern West Virginia are consistent with my review of defendants' distribution to pharmacies in the City of Huntington and Cabell County. I have asked SLCG to compile ARCOS data for prescription oxycodone and hydrocodone distributions to the West Virginia pharmacies identified in the Committee's report.

Pharmacy	**Dosage Units**[114]
Westside Pharmacy Oceana, WV DEA #BW9777559	7,538,690
Family Discount Pharmacy, Inc. 360 Mount Gay Road Mount Gay, WV DEA #BF0660565	15,544,160
Strosnider DBA Sav-Rite Pharmacy 50 Lincoln Street Kermit, WV DEA #BS7437064	13,169,550
Hurley Drug Company, Inc. 210 Logan Street Williamson, WV DEA #BH6954401	9,869,830
Tug Valley Pharmacy, LLC 54 w. 2nd Ave. Williamson, WV DEA #FT0251227	9,827,750
Beckley Pharmacy	2,307,700

[114] McCann Report, App. 10(B).

455 Stanaford Road Beckley, WV DEA #BB8263066	
Family Discount Pharmacy of Stollings, Inc. 153 Stollings Ave. Logan, WV DEA #BF1736567	3,308,400

One or more of each of Cardinal Health, McKesson, and AmerisourceBergen distributed to these pharmacies between 2006 and 2014. As the E&C Committee found, the amount of opioids distributed to these pharmacies in tiny West Virginia towns was extremely disproportionate to what could be considered legitimate use. This volume, in addition to the failures identified by the E&C Committee with respect to the defendants' due diligence, threshold setting processes, and suspicious order reporting support my opinion that Cardinal Health, McKesson, and AmerisourceBergen failed to maintain effective controls against the diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1).

N. MAINTENANCE OF EFFECTIVE CONTROLS AGAINST DIVERSION OF CONTROLLED SUBSTANCES

Registrants engaged in actively distributing controlled substances must implement measures to comply with the legal and regulatory requirements. These measures should be documented as a standard operating policy for the company and be distributed to all relevant employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see in an operational system designed to maintain effective controls against diversion:

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical first step to ensures a potential customer has a business plan consistent with compliance with the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:

- Past history of DEA registration to determine compliance history
- Check of state and local licensure compliance.
- Compliance history with state medical/pharmacy board
- Review the business plan to determine legitimacy of the customer
- Identify any affiliation with pain management doctors
- Review percentage of controlled substance business
- Identify any other distributors providing controlled substances
- Review the percentage of cash payments and insurance payments
- Review of pharmacy utilization reports
- On-site inspection of customer
- Internet search to determine any negative information

- 21 C.F.R. §1301.74(b) requires all manufacturers and distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances. This regulation states that suspicious orders include orders of an unusual size, orders deviating substantially for a normal pattern, and orders or an unusual frequency. The regulation further states that a registrant shall inform the local DEA Division Office of suspicious orders when discovered by the registrant. The regulation indicates it is the responsibility of the registrant to **design** and **operate** a suspicious order monitoring system. The design of a suspicious order system must clearly identify when a suspicious order is identified by the system. A system that establishes thresholds that are legitimate needs of a customer identified through a comprehensive "know your customer" should consider any orders exceeding that threshold as a suspicious order. The identified order should not be shipped and should be reported to the DEA. The subsequent shipping of that order would be after a due diligence investigation has determined the order is being shipped for legitimate use. An effective suspicious order monitoring system should include, but not be limited to, the following:

    - Customer Types – Customers should be placed into customer types based on the business activity identified through the due diligence documentation.
    - Scope of Practice – The system should monitor and/or restrict customers to only allow the ordering of controlled substances by schedule and type which have been identified as required for the legitimate medical needs of the practice.
    - Customer Tiers/Groups – Customers who have been placed into customer types should be segregated by size into a minimum of three groups, based on the volume of their ordering history as identified through the due diligence documentation.
    - Drug Types – To be effective, a suspicious order monitoring system should design drug types with more specificity that by drug group or drug code. Monitoring controlled substances only by the drug code or drug family is too broad and reduces the effectiveness of the system. Thresholds should also be designed for those controlled substances identified with a higher probability of being targeted for diversion.
    - Thresholds – A distributor must identify the amount of controlled substances required by a customer for the legitimate operation of their business based on the

registrant's knowledge of the customers business model, due diligence investigation, and comparison of purchase amounts by other similar customers. Thresholds should be calculated based on the history of usage of a customer for a period of at least 12 months.

- Population – The geographic distribution of controlled substances should be analyzed with relevant population information of available end users. The cumulative amount of controlled substances being distributed by a registrant to a geographic area or region should be monitored to ensure it is consistent with legitimate population consumption. Customers who identify activity of filling prescriptions from patients traveling from outside the area require a thorough due diligence type investigation including the review of dispensing records (without patient information) to confirm the legitimacy of the activity.
- Pattern of Orders – Reviewing orders to determine if there are patterns of ordering of controlled and non-controlled drugs with a comparison with relevant industry information on the most frequently prescribed drugs. If the review reveals an ordering pattern that deviates from established levels or from what would be normal for another similarly situated customer, this could indicate potential diversion.
- Pattern of Orders - Reviewing orders to determine if controlled substances are ordered in combinations of frequently abused drugs. As an example, purchasing the combination of oxycodone or hydrocodone products with Soma, Valium, and/or Xanax. The pattern of ordering of known highly abused controlled substances in comparison of other drugs can indicate diversion.
- Frequency of Orders – Reviewing orders to determine if the frequency of orders for controlled substances has increased disproportionately for specific controlled substances that have been identified as being highly diverted.
- Geographic Distribution – The density of like businesses in geographic areas should be reviewed. Further, there should be a comparison of like customers in similarly situated geographic areas for deviation of volume and/or pattern of controlled substance orders. The system should identify a large volume of controlled substances consistently being received from a customer(s) in a state, county and city/township that does not have the appropriate customer base density.

- A robust and well-documented due diligence program is key for every compliance system to identify suspicious orders of controlled substances. When orders of controlled substances are identified due to factors such as size, pattern, or frequency, those orders may only be shipped if any suspicion is dispelled after adequate due diligence is conducted, and it is determined that such orders are not likely to be diverted for illicit purposes. The elements and procedures involved in a due diligence compliance program for suspicious orders should be contained in a standard operation policy and should be readily available to all employees whose responsibilities touch on suspicious order monitoring. Characteristics of a robust due diligence program should include the following:

    - An established procedure and criteria for setting threshold quantities.

- The person or department who is responsible for approving threshold quantities is specifically identified.
- A procedure for adjusting threshold quantities that requires thorough review and documentation.
- Justification for the increase or decrease of thresholds documented by the registrant, and made after a review of factors such as the following:

    - Analysis of historical orders from the customer as well as any previous adjustments in thresholds and the justification previously provided;
    - Analysis of the patient population serviced by the customer;
    - Analysis of the physician population serviced by the customer;
    - Analysis of the results of an adequate on-site customer review program; and,
    - Analysis of other factors that could indicate to the registrant whether or not controlled substances are likely to be diverted for illicit purposes.

- Compliance review programs that have independent authority from other corporate entities/divisions to review thresholds as well as to approve or disapprove customers or threshold adjustments.
- Sales role (if any) in the compliance review program must be appropriately managed.
- On-site review includes the acquisition and review of utilization report.
- Request for threshold changes necessitates an on-site review.
- The person(s) is specifically identified who is responsible for reporting suspicious orders to the DEA.
- Orders reported as suspicious that are subsequently shipped by the registrant have sufficient due diligence review being conducted and documented prior to distribution.
- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.
- Acquisition and review of prescriber reports to determine any unusual prescribing patterns or practices, to be analyzed for the following information:
    - A disproportionate ratio of controlled to non-controlled substances prescriptions relative to the prescriber's field of practice or local population.
    - A prescriber issuing prescriptions for high volumes of controlled substances or disproportionately large volumes of controlled substances relative to the prescriber's field of practice.
    - Large variances or sharp increases in controlled substances prescribing.

- A high ratio of high dose or highly abused controlled substances prescriptions issued by a prescriber when compared to other strengths of the same drug type.
- Whether a practitioner or small number of practitioners are responsible for issuing a large amount of controlled substances prescriptions that are dispensed by the pharmacy.
- Prescriber who issues similar prescriptions of the same type, strength, and quantity with the same directions for a large number of patients.
- Prescriptions issued by a prescriber whose practice is an unusual distance from the pharmacy.
- Prescriptions issued for an unusual volume or pattern of antianxiety/antidepressants along with opioids.
- A high percentage of controlled substances paid for with cash/credit cards.
- Practitioners who issue prescriptions for a "cocktail" of controlled substances which are known in the medical and pharmacy professions as being favored by drug-seeking individuals.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions and information of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to make informed decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all.[115]

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships the order anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular

[115] Thomas Prevoznik testified on behalf of the DEA that it would be "very hard to maintain effective controls" without maintaining and retaining due diligence files. *See* Depo. of Prevoznik (Vol III; May 17, 2019), pp. 994-996.

pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs, because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

IV. Identifying Suspicious Orders Distributed in the City of Huntington and Cabell County, West Virginia

I have described in this report the ways in which Cardinal Health, McKesson, and AmerisourceBergen's inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed six suspicious order methodologies, some of which were utilized by one or more of the defendants. These methodologies are identified in the Report of Craig J. McCann as "Maximum Monthly, Trailing Six-month Threshold," "Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold," "Twice Trailing Twelve-month Average," "Three Times Trailing Twelve-month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not have been shipped unless the distributors' due diligence eliminated the suspicion of diversion.

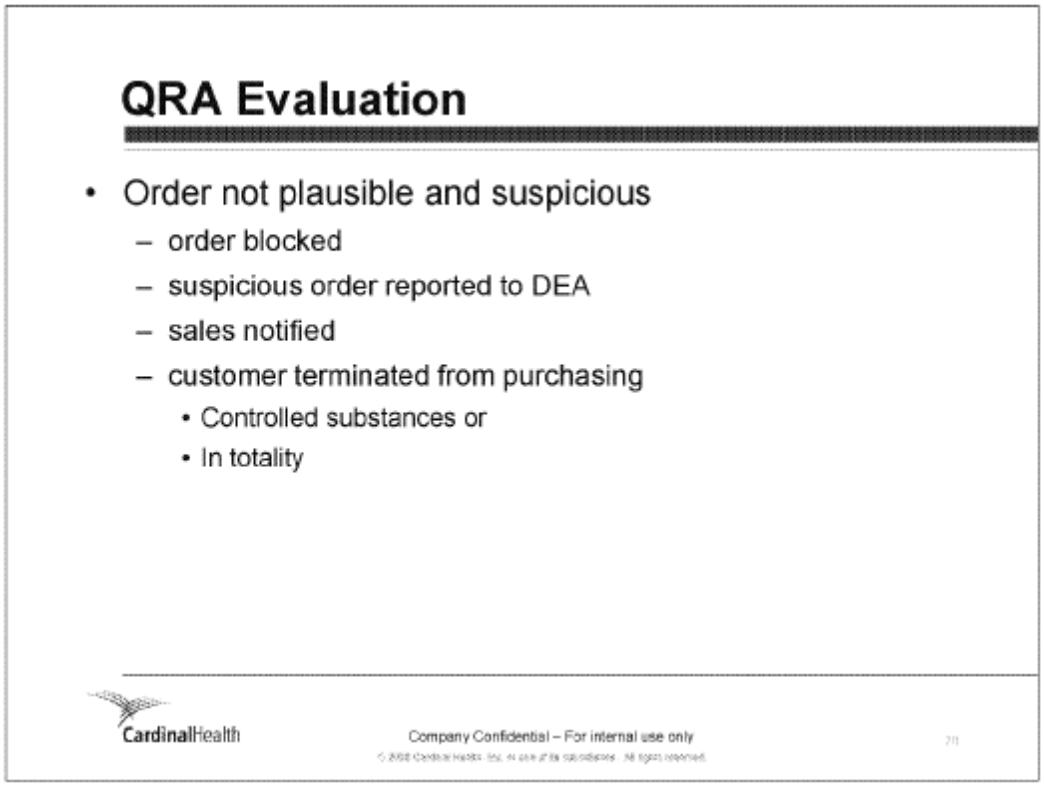
With the exception of the method titled Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold,[116] under each of these methodologies, once an order by a pharmacy is flagged and the distributor does not conduct sufficient due diligence to dispel the suspicion of diversion, each subsequent order by that pharmacy is also flagged. The failure to conduct adequate due diligence on the initial triggering order, means that all subsequent orders by that pharmacy are likewise suspicious. This is consistent with the testimony of Thomas Prevoznik who testified on behalf of the DEA that distributors should not ship a suspicious order and should terminate all future sales to that same customer until they can rule out that diversion is occurring.[117] This is also consistent with Cardinal Health's statement in *Cardinal Health, Inc. v. Holder*, 1:12-cv-00185, that "as early as 2009" Cardinal's policy was to "terminate controlled-substance sales to the customer and report the termination to DEA" if the "customer's order could not be filled because it was suspicious[.]"[118] Cardinal also trained its people on this very same approach. The slide below is from one of Cardinal's training presentation in which they indicate that if a

[116] Under the Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold, when a transaction causes the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to the pharmacy in any one of the six preceding months, the dosage units of highest month in the preceding six months becomes threshold which is then applied in all subsequent months.

[117] Depo. of Thomas Prevoznik (Vol. II), 627:7-629:15.

[118] CAH_MDL_PRIORPROD_DEA12_00014702, 719.

suspicious order is triggered it should be reported and the customer would be cut off altogether, or at least from purchasing controlled substances.[119]



McKesson likewise stated in its SMP Operations Manual that its policy was to cease all controlled substance sales to a customer once an order by that customer was deemed suspicious.[120]

Each method would have identified a significant volume of orders of opiates as shown in the tables below.

Cabell County and City of Huntington: 1996-2018[121]

A. Maximum Monthly, Trailing Six-month Threshold

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	11,610,920 (90.6% of total dosage units)	20,621,360 (91.1% of total dosage units)

[119] CAH_MDL2804_00227518, 587.

[120] MCKMDL00409224, 239.

[121] McCann Report, App. 7.

Cardinal Health	15,997,400 (93.1% of total dosage units)	14,795,350 (82.5% of total dosage units)
McKesson	3,501,970 (87.9% of total dosage units)	3,261,250 (87.4% of total dosage units)

B. Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	3,763,580 (29.4% of total dosage units)	5,616,380 (24.8% of total dosage units)
Cardinal Health	11,325,200 (65.9% of total dosage units)	7,252,580 (40.5% of total dosage units)
McKesson	805,300 (20.2% of total dosage units)	2,390,800 (64.0% of total dosage units)

C. Twice Trailing Twelve-month Average

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	10,477,680 (81.8% of total dosage units)	18,877,140 (83.4% of total dosage units)
Cardinal Health	14,011,880 (81.5% of total dosage units)	16,593,780 (92.6% of total dosage units)
McKesson	2,405,620 (60.4% of total dosage units)	2,362,420 (63.3% of total dosage units)

D. Three Times Trailing Twelve-month Average

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	8,360,740 (65.3% of total dosage units)	15,701,930 (69.4% of total dosage units)
Cardinal Health	9,567,580 (55.7% of total dosage units)	14,957,360 (83.5% of total dosage units)

McKesson	1,005,320 (25.2% of total dosage units)	1,245,640 (33.4% of total dosage units)

E. Maximum 8,000 Dosage Units Monthly

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	10,446,280 (81.5% of total dosage units)	21,679,760 (95.8% of total dosage units)
Cardinal Health	13,274,080 (77.2% of total dosage units)	16,159,150 (90.2% of total dosage units)
McKesson	2,098,560 (52.7% of total dosage units)	2,484,640 (66.6% of total dosage units)

F. Maximum Daily Dosage Units

	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen	12,459,020 (97.3% of total dosage units)	22,582,020 (99.8% of total dosage units)
Cardinal Health	16,527,880 (96.2% of total dosage units)	17,688,100 (98.7% of total dosage units)
McKesson	3,713,000 (93.2% of total dosage units)	3,648,650 (97.7% of total dosage units)

I have been asked to identify the number of opioid pills that entered Huntington and Cabell County unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.[122] However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[123] *See* Methodologies A and B above. Pursuant to *Masters*, "as a matter of common sense and ordinary language, orders that deviate

[122] This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the Distributor-specific sections of this report.

[123] This approach does not take into consideration unusual pattern or frequency.

from a six-month trend are an 'unusual' and not 'normal' occurrence" *Id.* at 216. I further opine that the controlled substances identified by the application of this algorithm would more likely than not be diverted from its intended use.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in Huntington and Cabell County. Methodologies A and B above are designed to identify orders of "unusual size" pursuant to 21 CFR 1301.74(b). Therefore, by definition, the orders identified by these methodologies are suspicious under the Controlled Substances Act and must be reported to the DEA. I have seen no evidence in the Defendants' productions provided to me that the Defendants conducted adequate due diligence on the orders identified in Methodologies A and B or reported the orders to the DEA as required by law. It is foreseeable that failing to comply with the Controlled Substances Act, specifically 21 U.S.C. § 823 et al., and 21 C.F.R. 1301.74, enables the diversion of controlled substances.[124] Congress has also declared that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people."[125] Based on my education, background, and experience, it is my opinion, to a reasonable degree of professional certainty, that the pills identified in Methodology A and B were more likely than not diverted and used for an illicit purpose.

My opinion on diversion is also supported by and consistent with other evidence in this case. West Virginia has the highest drug overdose death rate in the country.[126] Jan Rader, Chief of the City of Huntington Fire Department, testified that people she has seen responding to overdose calls have told her that their use of opioid pills began with prescription pills obtained with a legal prescription and then moved to buying pills illegally.[127] While Chief Rader testified that she sees all sorts of "prescription" opioids in her role, the most common types of opioids she sees on the street are hydrocodone and oxycodone.[128] Captain Rocky Johnson, who worked for the Huntington Police Department for 28 years, focused on drug-related crimes from 2012 until his retirement in 2019, found that one of the primary illegal drugs he was seeing on the street in

[124] Prevoznik Depo. (Vol. II), 642:3-643:1.

[125] 21 U.S.C. § 801(2).

[126] United States, Congress, House, Committee on Energy and Commerce. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, p. 4 (available at https://republicans-energycommerce.house.gov/wp-content/uploads/2018/12/Opioid-Distribution-Report-FinalREV.pdf) (last visited August 3, 2020).

[127] Depo. of Rader, 32:7-19.

[128] Depo. of Rader, 68:3-22.

2012 was Oxycontin.[129] Until his retirement Captain Johnson continued to see "diverted opioids" on the streets of Huntington.[130]

V. Opioids in West Virginia

It is my opinion that the amounts of opioids distributed into Cabell County, Huntington, and the State of West Virginia greatly exceeded what would be reasonable when compared to other locations..[131] In my opinion, the disproportionate volume of opioids distributed into these areas should have triggered immediate action by Cardinal, McKesson and AmerisourceBergen.

According to 2006-2014 ARCOS data, West Virginia received, per capita, the third highest amount of oxycodone and hydrocodone by dosage units in the nation, averaging 72.03 dosage units per capita per year. In comparison, Illinois, with a population roughly seven times that of West Virginia, ranks 46th in the country, averaging 27.00 oxycodone and hydrocodone dosage units per capita per year. Texas's population is 16 times West Virginia's and it ranks 35th and averaged 33.5 oxycodone and hydrocodone dosage units per capita per year. And Idaho, with a population similar to West Virginia's, ranks 25th, with 40.11 oxycodone and hydrocodone dosage units per capita per year.

Rank[132]	**Year**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**Average**
3	WV	58.48	67.13	74.32	76.73	74.09	77.29	76.69	72.85	70.71	72.03
25	ID	31.23	32.05	34.4	36.16	41.17	45.22	47.23	46.93	46.61	40.11
35	TX	28.11	32.98	32.23	33.87	35.13	37.36	35.97	34.51	31.36	33.5
46	IL	24.26	26.05	28.03	22.79	25.76	28.7	29.24	29.33	28.8	27

Cabell County, which includes the City of Huntington, received the eighth most oxycodone and hydrocodone by dosage units, per capita, of all West Virginia counties from 2006-2014, according to ARCOS data.

Rank[133]	**State**	**County**	**Population**	**Oxycodone**	**Hydrocodone**	**2 drug Total**	**per capita, per year**

[129] Depo. of Johnson, 14:14-15:8; 33:6-33:17.

[130] Depo. of Johnson, 35:17-36:7.

[131] *See Direct Sales Co. v. United States*, 319 U.S. 703 (1943) (CAH_MDL_PRIORPROD_DEA07_01178176).

[132] McCann Report, App. 9(I).

[133] McCann Report, App. 10(D).

8	WV	Cabell	96,037	23,412,160	51,852,360	75,264,520	87.08

In addition to the excessive distributions into Cabell County/Huntington and West Virginia, the Defendants were aware that an influx of even more opioids were making their way into West Virginia from Florida and other states via the route often referred to as the "Oxy Express" or "Blue Highway." Since at least the late 2000's, residents of the Appalachia region have traveled to Florida to obtain prescription opioids in Florida and bring them back to their home area for illicit purposes. The pills could be sold in the region for many times what they were purchased for in Florida. Documents produced by Plaintiffs show that the pills from Florida made their way into Cabell County and Huntington.

- A 2012 Huntington Police Department Threat Assessment and Strategy Summary stated that:

  In 2011, scores of residents in an around Huntington travelled out of the area, mainly to south Florida, to obtain thousands of dosage units of strong narcotic and other prescription drugs and transported them back to Huntington for use and distribution.[134]

- In 2012 the Huntington Police Department advised that:

  Looking at prescription drugs a new variation of the Oxy family of drugs with a brand name of Opana (Oxymorphone) has increased in popularity over the past year. Huntington has seen multiple overdose deaths due to Opana during this time. Most of the prescription medications are trafficked through Florida, into Kentucky and Ohio, then onto West Virginia.[135]

- In March 2009, the Cabell County Sheriff's Department arrested individuals with $20,000 worth of Oxycodone (at least 548 pills) and receipts showing subjects had been to pain clinics in Fort Lauderdale, FL.[136]

- In November 2009, the Cabell County Sheriff's Department located a woman who was reported missing after traveling to Florida with a man to obtain Oxycodone pills. She was located at a local motel with large amounts of cash, a card from a pain clinic in Florida, driving directions to Florida, a pharmacy receipt from Florida, and multiple bottles of prescription pills including Roxicodone and Xanax. The daughter admitted to driving to Florida to obtain pain medication on multiple occasions.[137]

[134] HUNT_00286731.

[135] HUNT_00029464.

[136] CCDS_0044668.

[137] CCDS_0029884.

- In April 2010, Huntington Police Department arrested a man with three partially full pill bottles in his possession for 60 2mg Alprazolam, 90 15mg Roxicodone, and 180 30mg Oxycodone pills. The prescriptions for the pills were filled the day before his arrest at a pain clinic in Florida. The man stated that he traveled to Florida every month to refill his prescriptions.[138]

- In September 2010, the Cabell County Sheriff's Drug Task Force executed a search warrant looking for prescription painkillers and found quantities of Oxycodone, Florida pain clinic business cards, driving directions to Florida pain clinics, 60 pill bottles, and over $13,000 in cash.[139] Evidence showed that over the course of 6 months the arrestees obtained over 4,300 controlled substance pills by getting prescriptions from Florida pain clinics with 90 percent of the prescriptions being written by one Florida doctor.[140]

- In December 2011, the Barboursville Police Department Drug Unit arrested a man and found Oxycodone and Oxymorphone prescription pills. The man arrested admitted to being sponsored for a trip to Florida in order to get pills from pain clinics in return for cash payments.[141]

Defendants were aware of the problem with pills migrating from Florida into Plaintiffs' area. In an October 2010 Cardinal QRA Compliance presentation, the presenter notes that "what is happening in the marketplace" is that pills "sold on the streets of Central Florida" it could "make its way north" and be sold for four times as much.[142] The same month, Cardinal VP of Anti-Diversion Michael Moné forwarded an article to Gilberto Quintero, Senior VP of QRA, pointing out a "key statement" that "49 of the top 50 dispensing doctors of oxycodone in the nation were in Florida."[143]

McKesson identified Florida as the state with the highest oxycodone dispensing in 2012.[144] In the same presentation, McKesson included a map showing the path of "Drug Diversion Migration Out of Florida" and into states bordering West Virginia.[145]

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[138] HUNT_00263760.

[139] CCDS_0028875.

[140] CCIRC_0303373, CCIRC_0303340.

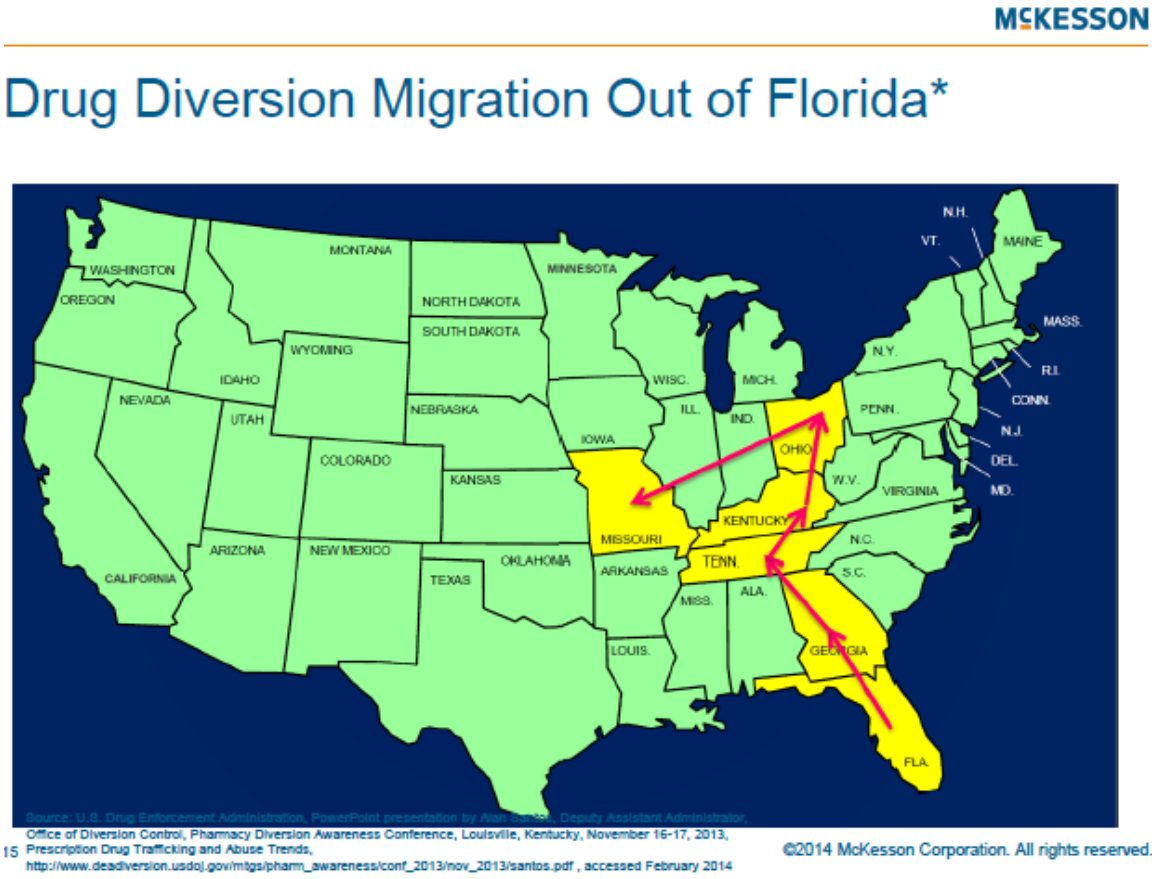
[141] HUNT_00730154 .

[142] CAH_ALASKA_00190590, 597.

[143] CAH_MDL2804_01103870.

[144] MCKMDL00407451, 460.

[145] *Id*. At 465.



AmerisourceBergen Director of Diversion Control and Security, Edward Hazewski, testified that he became aware of the problem of pills migrating from Florida into West Virginia as early as 2008 when he became manager of AmerisourceBergen's diversion control team.[146] AmerisourceBergen's corporate designee, Christopher Zimmerman, testified that the company was aware of the problem of pill migration as early as 2007, as shown by a comic strip included in an AmerisourceBergen presentation on its "Diversion Control Program."[147]

VI. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process, I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

[146] Depo. of Edward Hazewski, 71:8-72:10.

[147] ABDCMDL00000124, 14; Depo. of Christopher Zimmerman, 336:13-336:24, 407:1-14

A. Cardinal Health

Distribution Center: Wheeling, WV

DEA Registrant Number: [redacted]

Transactional Data Disclosed: Date range: 01/01/1996 through 05/01/2018[148]

Cabell County/Huntington Volume: [149]

Oxycodone	17,187,905 dosage units
Hydrocodone	17,923,260 dosage units

1. Court ordered SOMS Discovery Disclosure:

- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' First Combined Discovery Requests* (July 31, 2018)
- *Cardinal Health, Inc.'s First Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests* (November 30, 2018)
- *Cardinal Health, Inc.'s Second Supplemental Objections and Responses To Plaintiffs' First Combined Discovery Requests* (January 22, 2019)
- *Cardinal Health, Inc.'s Third Supplemental Objections and Responses To Plaintiffs' First Combined Discovery Requests* (March 4, 2019)
- *Cardinal Health, Inc.'s Objections and Responses to Track 2 Plaintiffs' (First) Combined Discovery Requests* (November 29, 2019)
- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' First Set of Requests for Production of Documents* (May 29, 2018)
- *Cardinal Health, Inc.'s Objections and Supplemental Responses to Plaintiffs' First Set of Interrogatories* (November 30, 2018)
- *Cardinal Health, Inc.'s Objections and Second Supplemental Responses to Plaintiffs' First Set of Interrogatories* (March 4, 2019)
- *Cardinal Health, Inc.'s Revised Objections and Third Supplemental Responses to Plaintiffs' First Set of Interrogatories* (March 25, 2019)
- *30(b)(6) Deposition of Cardinal Health (Jennifer Norris)* (August 7, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topic 1* (September 11, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics (O), 9-11* (October 18, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topic 2* (October 25, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics 3-5* (November 9, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics 13, 15-21* (November 14, 2018)

[148] CAH_MDL2804_03468430.

[149] McCann Report, App. 7.

- *Cardinal Health's Supplemental Written Response to Plaintiffs' 30(b)(6) Topic (a)* (January 24, 2019)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics 16-18* (January 24, 2019)
- *Cardinal Health's Revised and Supplemental Written Response to Plaintiffs' 30(b)(6) Topic (a)* (March 4, 2019)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topic 14* (March 4, 2019)
- *Cardinal Health, Inc.'s Objections and Responses to Track 2 Plaintiffs' (First) Combined Discovery Requests* (November 29, 2019)
- *Cardinal Health, Inc.'s Second Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests* (March 18, 2020)
- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' Second Combined Discovery Requests* (March 30, 2020)
- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' Third Combined Discovery Requests* (April 8, 2020)
- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' Fourth Combined Discovery Requests* (April 30, 2020)
- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' Fifth Combined Discovery Requests* (May 6, 2020)
- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' Sixth Combined Discovery Requests* (May 11, 2020)
- *Cardinal Health, Inc.'s Third Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests* (May 14, 2020)
- *Cardinal Health, Inc.'s Supplemental Objections and Responses to Plaintiffs' Sixth Combined Discovery Requests* (June 2, 2020)
- *Cardinal Health, Inc.'s Fourth Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests* (June 2, 2020)
- *Cardinal Health, Inc.'s Fifth Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests* (July 9, 2020)
- *Cardinal Health, Inc.'s Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests* (July 10, 2020)
- *Cardinal Health, Inc.'s Sixth Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests* (July 16, 2020)
- *Cardinal Health, Inc.'s Third Supplemental Objections and Responses to Plaintiffs' Sixth Combined Discovery Requests* (July 16, 2020)

2. <u>SOMS Corporate Policy Disclosed</u>:

Cardinal Health DEA Compliance Manual (April 5, 2000)[150]

This system that Cardinal used from April of 2000 until sometime in late 2007/early 2008 had two operational aspects. First, Cardinal Health utilized the Ingredient Limit Reports, which

[150] CAH_MDL_PRIORPROD_DEA07_01383895, 01383939-01384041.

were generated as a retrospective review of the prior month's distribution data based on a formula that was applied on a monthly basis. A hard copy was then mailed to the local DEA office. According to Mr. Reardon, Vice President Quality and Regulatory Affairs from 2005 to 2007 and a Director in regulatory prior to 2000, this system was utilized by Cardinal as far back as the early 1990's.[151] The second part of this system was to have cage/vault employees looking for suspicious orders based on the "Excessive Purchases Schedule II" and "Excessive Purchases Schedule III, IV, V" charts.[152] If Cardinal's pickers and checkers spotted an excessive order, they were to notify the local DEA office prior to shipment of the order if possible and place a copy of these orders in the distribution center's suspicious order file along with a Regulatory Agency Contract Form (Form #1) noting any specific instructions from the DEA.[153]

Cardinal SOM Program (12/01/2007 through 12/22/2008) [154]

The next step in the evolution of Cardinal's SOM Programs is unclear. According to document CAH_MDL2804_01522227, Cardinal's policies changed on this date to incorporate threshold and a know your customer (KYC) system. However, according to sworn testimony for Cardinal via its 30(b) designee Jennifer Norris, Cardinal does not know what changes it made within its SOM systems from September 2006 through at least late 2007.[155]

Cardinal SOM Program (12/22/2008 to 2012)[156]

In 2008 Cardinal implemented several Standard Operating Procedures (SOPs) related to anti-diversion. This system also had two primary components. The first component was threshold utilization. This included setting a specific threshold (based on dosage unit) for each customer for each controlled drug base code or drug family and if the customer exceeded the allotted threshold the order was to be held and not shipped. The second component to this system was "Know Your Customer" (KYC) and it obligated Cardinal to know who they were dealing with. The threshold process and KYC are discussed in more detail in other portions of my report.

Cardinal SOM Program (2012 forward)

Beginning around 2012/2013, Cardinal's system continued to rely on the threshold and KYC/due diligence components, but it no longer took into consideration the population of the area

[151] *See* Deposition of Steve Reardon, November 30, 2018 at 410: 10 to 411: 11 and 429: 3-10.

[152] *See* CAH_MDL_PRIORPROD_DEA07_01383136, 01384160-01384161.

[153] CAH_MDL_PRIORPROD_DEA07_01383895, 01383940 and 01384080.

[154] CAH_MDL2804_01522227

[155] *See* Deposition of Jennifer Norris, page 292.

[156] CAH_MDL_PRIORPROD_AG_0004208, CAH_MDL_PRIORPROD_AG_0000323, CAH_MDL_PRIORPROD_AG_0000344, CAH_MDL_PRIORPROD_AG_0000101, CAH_MDL_PRIORPROD_DEA12_00014535, 00014536; CAH_MDL_PRIORPROD_AG_0000013

surrounding a customer nor did it compare customers to similar customers. The revised system based threshold solely on the individual customer's information.[157]

3. Enforcement Actions

a) On December 26, 2006, Cardinal entered into an Assurance of Discontinuance Pursuant to Executive Law §63(15) with the NY AG related to its failures to prevent and monitor price diversion and closed door pharmacies;[158]

b) On September 18, 2007, the DEA issued a *Warrant for Inspection* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;[159]

c) On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;[160]

d) On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;[161]

e) On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;[162]

f) On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;[163]

g) On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The

[157] *See* Depo. of Todd Cameron, pages 54-69.

[158] CAH_MDL_PRIORPROD_DEA07_00833777.

[159] CAH_MDL2804_02110916, 02110918-02110923.

[160] CAH_MDL2804_00641449, 00641465.

[161] CAH_MDL2804_00641449, 00641469.

[162] CAH_MDL2804_00641449, 00641474.

[163] CAH_MDL2804_00641449, 00641479

document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at all 27 of Cardinal's distribution centers nationwide;[164]

h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;[165] and

i) On December 22, 2016, Cardinal Health subsidiary Kinray, LLC entered into a Consent Order with the United States.[166]

j) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.[167]

4. Suspicious Orders Reported In the City of Huntington and Cabell County, West Virginia[168]

	Pre-Shipment Reporting	Post-Shipment Reporting
1996	0	
1997	0	
1998	0	
1999	0	
2000	0	
2001	0	
2002	0	
2003	0	
2004	0	
2005	0	ILRs
2006	0	ILRs
2007	0	ILRs
2008	0	ILRs (April only)
2009	0	
2010	1	

[164] CAH_MDL2804_00641449.

[165] CAH_MDL2804_02465982.

[166] *United States of America v. Kinray, LLC*, Case #16 Civ. 8767-RA. Available at https://www.justice.gov/usao-sdny/press-release/file/920806/download (last visited August 3, 3030).

[167] CAH_MDL2804_02069030.

[168] CAH_MDL2804_03468434.

2011	0	
2012	115	
2013	86	
2014	5	
2015	19	
2016	34	
2017	32	
2018	0	

5. Due Diligence Conducted

Due Diligence is one of the core components of any SOMS and must be fully integrated if the SOMS is going to work adequately. The basic premise for due diligence is that a registrant must know who they are dealing with when distributing controlled substances (potentially dangerous drugs) into surrounding communities. Cardinal's due diligence system has evolved over time and while it has made general improvements in theory the overall application of the system does not meet its regulatory requirement to maintain effective controls against diversion.

Cardinal's due diligence prior to 2008 was very limited, and it is difficult to discern exactly what due diligence was conducted by Cardinal prior to 2008. Cardinal produced documents CAH_FEDWV_00000001 – 00001109 it identified as centralized due diligence files for Cardinal customers in Huntington and Cabell County. Additionally, Cardinal's Sixth Supplemental Objection and Response to Plaintiffs' First Combined Discovery Requests identified additional, non-centralized due diligence documents, It appears that prior to 2008 Cardinal's customer due diligence was limited. It appears that Cardinal's early due diligence solely sought to ensure compliance with 21 CFR 1301.74(a) which reads in pertinent part:

> Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substance registration agency, if any, to determine that the person is registered to possess the controlled substance.

While such due diligence is a first step in the process, it does not meet the required level of compliance to ensure a sufficient level of maintenance of effective control by which a registrant should operate.

In 2005 it appears that the NY AG began an investigation of Cardinal related to the distribution of its products.[169] This matter involved, amongst other allegations, price diversion with closed door pharmacies that engaged in contract pricing. This matter resolved in December of 2006 with the entry of an Assurance of Discontinuance. This appears to have caused Cardinal to create its first customer screening and monitoring process at least as it applies to "closed-door

[169] *See* CAH_MDL_PRIORPROD_DEA07_00833777.

pharmacy customers at contract pricing."[170] This policy is very limited in its application to "closed-door pharmacy customers at contract pricing," and there was no indication that a like policy was enacted for Cardinal's remaining customers. The main function of this policy as it relates to due diligence was to require a "Contract Pricing Declaration" and a "Site Visit Form." This process did not constitute adequate due diligence for these customers. Additionally, it appears that these forms were not utilized prior to 2006, confirming the lack of due diligence even for closed-door pharmacies prior to that date.[171]

In 2007/2008, when Cardinal was being investigated by the DEA and received immediate suspension orders for three of its distribution centers, I see the next significant change in the due diligence process in place at Cardinal. This is first demonstrated in a training manual that was prepared by Eric Brantley (at least the manual bears his name) and dated October 2007 and is titled Know Your Customer Program: Retail Pharmacy Questionnaire Training.[172] There is also a related document that is an email from Gary Cacciatore sent on December 9, 2007, indicating this training was being rolled out to the "independent retail sales team" to be completed by December 19, 2007.[173] For this time frame up until 2012 there appears to have been some due diligence/know your customer functions occurring in Huntington and Cabell County for retail independent pharmacies/drug stores but not to the extent I have outlined above.

During this same time, 2007/2008 to 2012, there seems to have been very little implementation of actual policies related to know your customer/due diligence.[174] Cardinal Health provided almost preferential treatment to its chain pharmacies/national accounts as compared to their retail independent customers. Cardinal Health's policies did not reflect this almost preferential treatment. Cardinal admittedly did not conduct the same due diligence on its chain customers during this time period.[175] This practice was not acceptable for maintaining effective controls against diversion and was a breach of Cardinal's obligation as a registrant. As indicated above, there was clearly some due diligence being conducted, some of which occurred in the way of on-site investigations, however, according to the Special Demand Committee Report of Cardinal's Board of Directors, those investigations were not being reviewed properly.[176] These requirements are not intended to be an act in futility but are a useful and necessary tool in meeting the registrant's regulatory requirements.

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[170] *See* CAH_MDL_PRIORPROD_DEA07_00871842.

[171] *See* CAH_MDL_PRIORPROD_DEA07_00008894.

[172] *See* CAH_MDL_PRIORPROD_DEA07_02738896.

[173] *See* CAH_MDL_PRIORPROD_DEA07_02738893.

[174] *See, e.g.*, CAH_FEDWV_00000001 - 00001109.

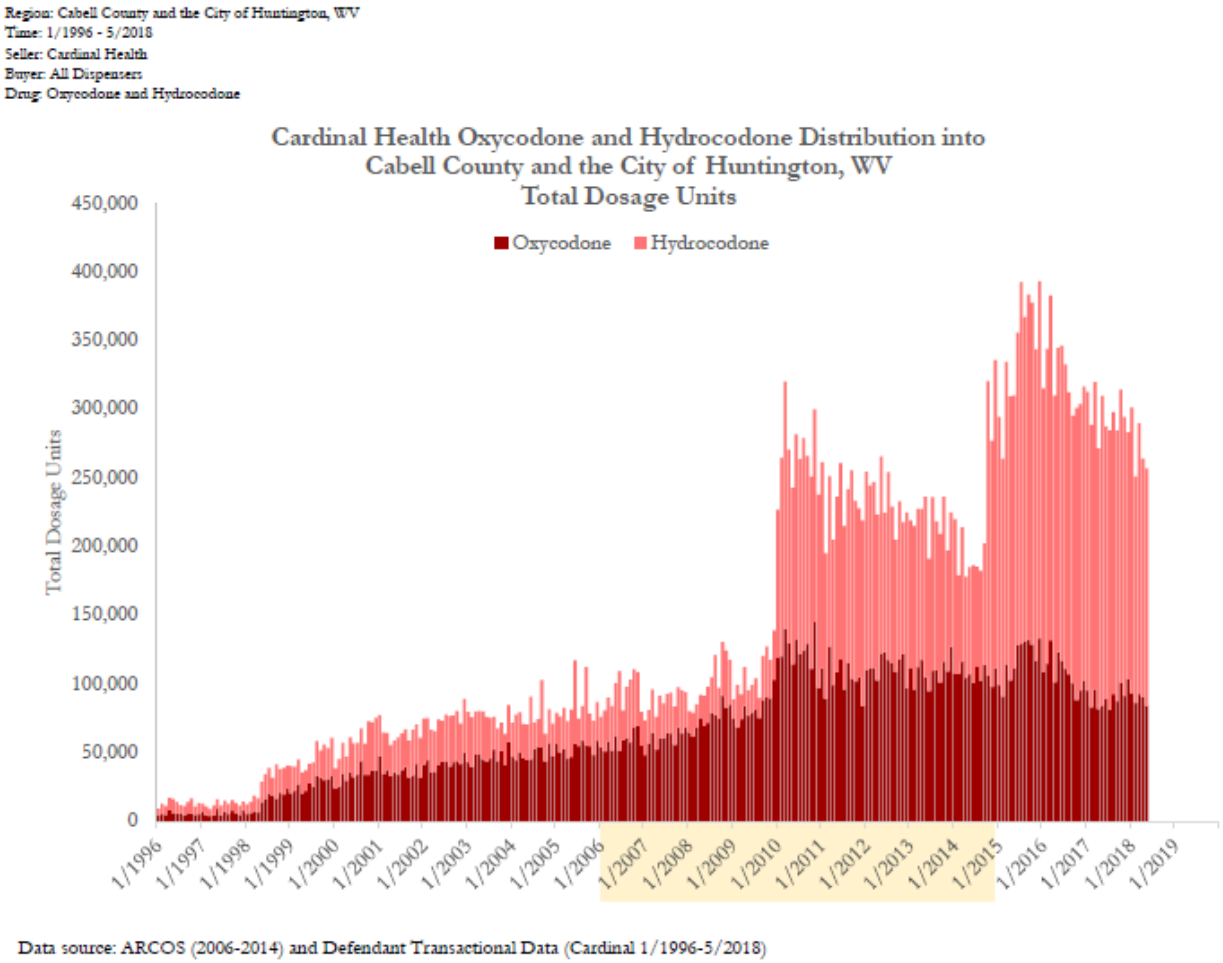
[175] *See* Declaration of Michael A. Mone, CAH_MDL_PRIORPROD_DEA12_00014053 at page 13.

[176] *See Investigation Report of the Special Demand Committee*, CAH_MDL_PRIORPROD_HOUSE_0003331 at page 36.

6. Opinions Related to Cardinal Health

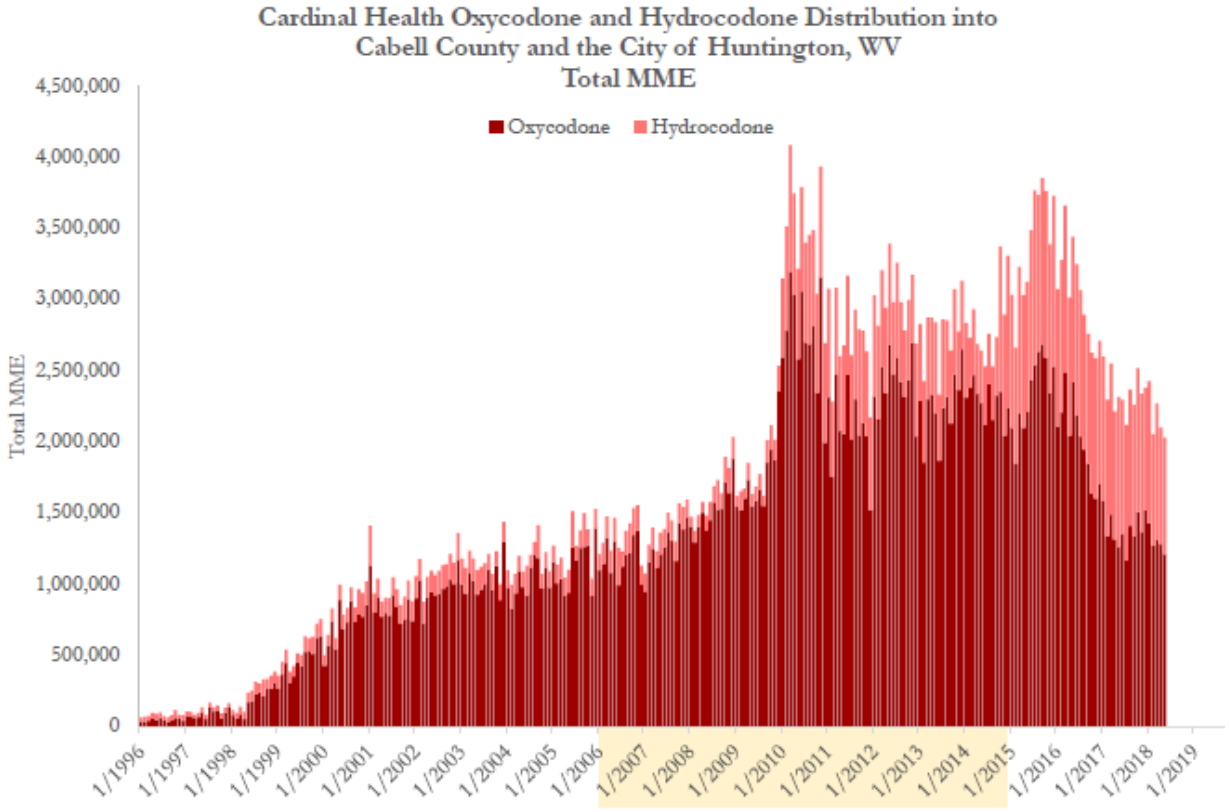
1. Cardinal Health failed to *maintain effective control* against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].

The graphs below demonstrate a clear increase of distribution of prescription oxycodone and hydrocodone by Cardinal into Cabell County and the City of Huntington, West Virginia by dose, base weight and MME.[177]



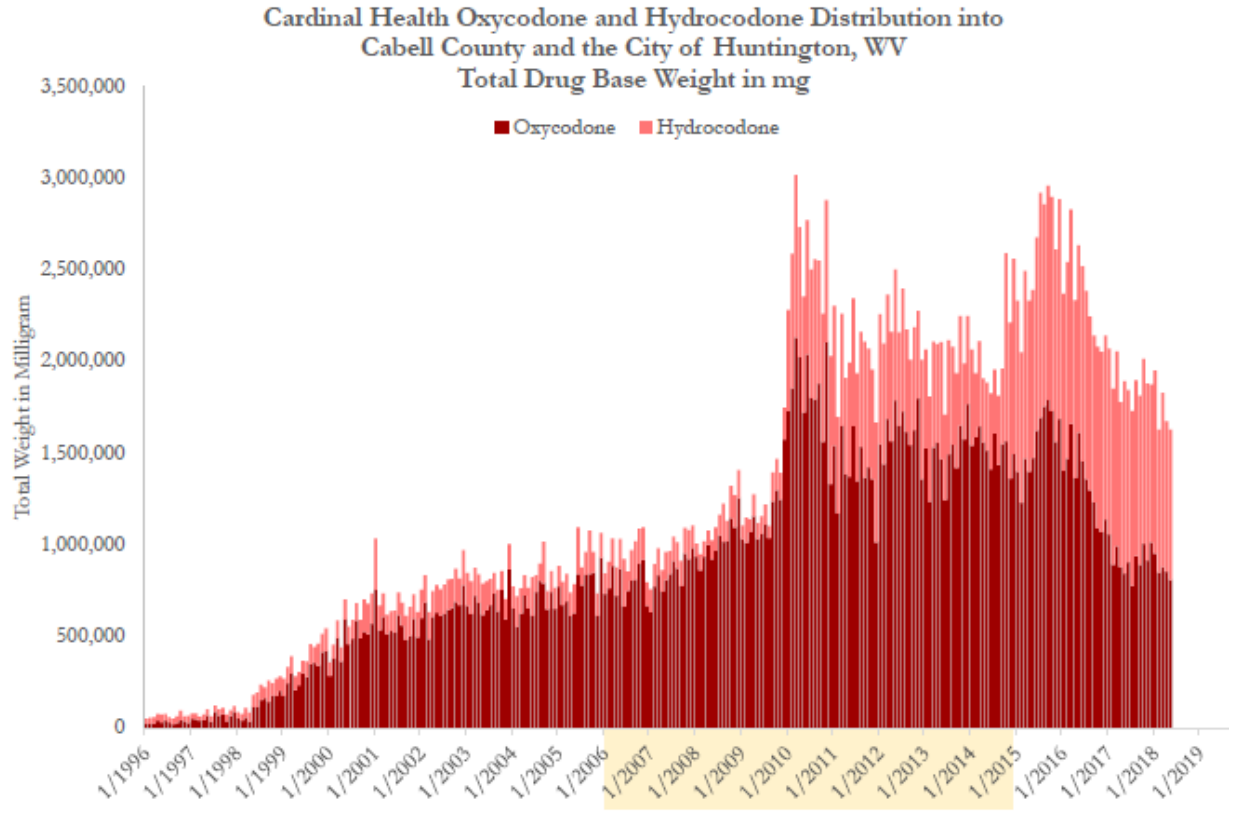
[177] McCann Report, App. 9(C).

Region: Cabell County and the City of Huntington, WV
Time: 1/1996 - 5/2018
Seller: Cardinal Health
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (Cardinal 1/1996-5/2018)

Region: Cabell County and the City of Huntington, WV
Time: 1/1996 - 5/2018
Seller: Cardinal Health
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (Cardinal 1/1996-5/2018)

In my opinion the massive increase in prescription opioids without sufficient due diligence documented is indicative of a failure to maintain effective control.

2. <u>Cardinal Health failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the *security requirement* set forth in 21 C.F.R. § 1301.74(b).</u>

a. Policy Period #1 (1996 to 2008):

i. **Ingredient Limit Reports**

Cardinal Health claims its system from 1996 to 2008 was premised upon "guidance" from the 1998 DEA Reno Report.[178] The record does not reveal any documentation which supports this

[178] Cardinal Health's Supplemental Response to Plaintiffs' First Combined Discovery Request No. 3 (November 30, 2018); Deposition of Jennifer Norris (30(b) Designee for Cardinal Health), 134:16-23.

contention.[179] Moreover, the Reno Report provides guidance on monitoring monthly orders of chemicals used to make illicit methamphetamine. The Reno Report, referencing the Chemical Handlers Manual, advises a distributor to set an "ingredient limit" as a tool to detect monthly orders of ***extraordinary*** size. This limit is determined by calculating a monthly average for similarly situated customers and multiplying by a factor of three (3). Monthly orders in excess of this limit are deemed "extraordinary" and must be reported.

Cardinal Health used this methodology to monitor controlled substances but used a factor of four (4) to identify ***unusual*** monthly orders. This design is insufficient to meet the security requirement because: (a) it fails to identify suspicious orders before shipment; (b) it uses after-the-fact reporting of suspicious orders; (c) it ships suspicious orders; and (d) it uses a 4x factor which is in excess of the factor discussed by the Reno Report to detect orders of ***extraordinary*** size. Cardinal Health knew or should have known that such a system, by itself, was woefully insufficient to meet its obligations under federal law.

I have reviewed a 2008 audit of Cardinal's suspicious order monitoring system, including Cardinal's use of Ingredient Limit Reports (ILRs), by Ronald Buzzeo of Cegedim Dendrite.[180] Among his conclusions were that because the ILRs were based on historical information they were not compliant with Federal suspicious order monitoring requirements as they did not allow for "real time automated analysis of pattern and frequency."[181]

If Cardinal Health designed its system in accordance with the DEA Diversion Investigators Manual (1996), a copy of which it had in its possession since after requesting it in 2003, it would have identified a serious problem in Huntington and Cabell County.[182] The Manual states:

> ***Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. The supplier can determine***

[179] *See* Deposition of Jennifer Norris (30(b) Designee for Cardinal Health); Cardinal Health's original and First, Second, and Third Supplemental Responses to Plaintiffs' Frist Combined Discovery Request; Cardinal Health's Written Original and Supplemental Responses to Plaintiffs' First Notice of 30(b) Deposition, Topic (a). Furthermore, while there is not necessarily evidence that the "guidance" Cardinal allegedly received was communicated by a DEA field agent, to the extent it was, pursuant to the reasoning in *Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689, n. 53 (Drug Enf't Admin. September 3, 2008), Cardinal's reliance on an agent's "erroneous understanding of the law and regulations" would have been misplaced..

[180] CAH_MDL2804_03309960.

[181] *Id*. at 961, 964.

[182] Cardinal also received the 2010 version of the Diversion Investigator's Manual in 2013. *See* CAH_MDL2804_00953317.

> ***whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.***[183]

Cardinal Health did not retain the algorithm nor the formula it used to calculate the average purchase of controlled substances by the distribution center servicing the City of Huntington and Cabell County, West Virginia.[184] However, Cardinal Health produced ILRs from its Wheeling Distribution Center from which the following "ingredient limits" of oxycodone and hydrocodone can be derived:

Bates Range	**Date**	**Limit for 9143**	**Limit for 9193**
CAH_MDL_PRIORPROD_DEA07_01465435 – 01465712 (*see* CAH_MDL_PRIORPROD_DEA07_01465497)	August 2005	137.03136	42.67696
CAH_MDL_PRIORPROD_DEA07_01713984 – 01714260 (*see* CAH_MDL_PRIORPROD_DEA07_01714045)	September 2005	134.53336	43.14248
CAH_MDL_PRIORPROD_DEA07_01676164 – 01676385 (*see* CAH_MDL_PRIORPROD_DEA07_01676206)	October 2005	140.26240	43.62120
CAH_MDL_PRIORPROD_DEA07_01640601 – 01640859 (*see* CAH_MDL_PRIORPROD_DEA07_01640661)	November 2005	140.00036	43.94216
CAH_MDL_PRIORPROD_DEA07_01698986 – 01699238 (*see* CAH_MDL_PRIORPROD_DEA07_01699031)	December 2005	138.63832	44.33880
CAH_MDL_PRIORPROD_DEA07_01554009 – 01554254	January 2006	136.70968	44.71368

[183] *See* CAH_MDL2804_02203353.

[184] *See* Special Master Cohen Discovery Hearing Transcript of January 25, 2019, pp. 60-67. This system applied to all Cardinal Health distribution centers. *See* Deposition of Steve Reardon, 456:2 – 456:20.

(*see* CAH_MDL_PRIORPROD_DEA07_01554060)			
CAH_MDL_PRIORPROD_DEA07_01538085 – 01538299 (*see* CAH_MDL_PRIORPROD_DEA07_01538126)	February 2006	134.12484	45.21144
CAH_MDL_PRIORPROD_DEA07_01611135 – 01611464 (*see* CAH_MDL_PRIORPROD_DEA07_01611192)	March 2006	131.07688	45.95936
CAH_MDL_PRIORPROD_DEA07_01641502 – 01641682 (*see* CAH_MDL_PRIORPROD_DEA07_01641540)	April 2006	127.79620	42.21564
CAH_MDL_PRIORPROD_DEA07_01788800 – 01789058 (*see* CAH_MDL_PRIORPROD_DEA07_01788850)	May 2006	125.41532	46.93344
CAH_MDL_PRIORPROD_DEA07_01590839 – 01591156 (*see* CAH_MDL_PRIORPROD_DEA07_01590908)	June 2006	122.04580	47.64656
CAH_MDL_PRIORPROD_DEA07_01573797 – 01574019 (*see* CAH_MDL_PRIORPROD_DEA07_01573850)	July 2006	119.70760	48.77660
CAH_MDL_PRIORPROD_DEA07_01475709 – 01475962 (*see* CAH_MDL_PRIORPROD_DEA07_01475761)	August 2006	117.42644	49.45828
CAH_MDL_PRIORPROD_DEA07_01723108 – 01723339 (*see* CAH_MDL_PRIORPROD_DEA07_01723159)	September 2006	114.11996	49.58536
CAH_MDL_PRIORPROD_DEA07_01685103 – 01685339 (*see* CAH_MDL_PRIORPROD_DEA07_01685159)	October 2006	112.16060	49.85244
CAH_MDL_PRIORPROD_DEA07_01650463 – 01650717	November 2006	109.56708	49.98252

(see CAH_MDL_PRIORPROD_DEA07_01650518)			
CAH_MDL_PRIORPROD_DEA07_01515965 – 01516204 (*see* CAH_MDL_PRIORPROD_DEA07_01516022)	December 2006	107.36024	49.75956
CAH_MDL_PRIORPROD_DEA07_01563313 – 01563602 (*see* CAH_MDL_PRIORPROD_DEA07_01563374)	January 2007	106.47764	50.03312
CAH_MDL_PRIORPROD_DEA07_01546013 – 01546207 (*see* CAH_MDL_PRIORPROD_DEA07_01546054)	February 2007	105.83396	50.16428
CAH_MDL_PRIORPROD_DEA07_01620843 – 01621127 (*see* CAH_MDL_PRIORPROD_DEA07_01620900)	March 2007	104.40680	50.17876
CAH_MDL_PRIORPROD_DEA07_01457031 – 01457282 (*see* CAH_MDL_PRIORPROD_DEA07_01457086)	April 2007	104.82816	50.70796
CAH_MDL_PRIORPROD_DEA07_01747160 – 01747495 (*see* CAH_MDL_PRIORPROD_DEA07_01747222)	May 2007	105.42900	50.98644
CAH_MDL_PRIORPROD_DEA07_01601686 – 01601970 (*see* CAH_MDL_PRIORPROD_DEA07_01601749)	June 2007	106.12548	50.75616
CAH_MDL_PRIORPROD_DEA07_01544958 – 01545544 (*see* CAH_MDL_PRIORPROD_DEA07_01545069)	July 2007	116.35200	50.83508
CAH_MDL_PRIORPROD_DEA07_01488350 – 01488972 (*see* CAH_MDL_PRIORPROD_DEA07_01488469)	August 2007	127.77312	52.07900
CAH_MDL_PRIORPROD_DEA07_01732427 – 01732872	September 2007	137.53468	52.34368

(*see* CAH_MDL_PRIORPROD_DEA07_01732511)			
CAH_MDL_PRIORPROD_DEA07_01696166 – 01696738 (*see* CAH_MDL_PRIORPROD_DEA07_01696272)	October 2007	148.22516	53.21820
CAH_MDL_PRIORPROD_DEA07_01660982 – 01661449 (*see* CAH_MDL_PRIORPROD_DEA07_01661075)	November 2007	158.34500	54.08492
CAH_MDL_PRIORPROD_DEA07_01525200 – 01525688 (*see* CAH_MDL_PRIORPROD_DEA07_0155294)	December 2007	166.08928	52.92888
CAH_MDL2804_00689780 – 00690378 (*see* CAH_MDL2804_00689879)	April 2008	211.60004	49.09028

Additionally, this chart exemplifies some of the concerns I have with Cardinal Health's SOMS. This ILR information is all from Cardinal Health's Wheeling distribution center, and we can see that for this geographic area the limiter amount for oxycodone is decreasing from October 2005 through March 2007, from 140.26240 down to 104.40680. Then, in April of 2007, the limiter begins to increase until April 2008 (did not have ILR's for January, February, and March of 2008), climbing from 104.82816 up to 211.60004, more than doubling the limiter for oxycodone in a year's time. It is my understanding that this distribution center provides distribution services to Ohio, West Virginia, and parts of Pennsylvania.[185] This drastic increase should have triggered an investigation to ensure the legitimacy of the orders placed by the customers for oxycodone.

ii. **Excessive Orders**

Cardinal Health's system (early 1990's-2008)[186] was also designed to identify "individual orders that appear to be excessive" on a daily basis and notify the DEA, if possible, before the order is shipped. Excessive orders are defined by the following dosage limits:

Hydrocodone	800 Tabs/Caps
Oxycodone / Acet (Tylox, Roxilox, Roxicet. Percocet. Endocet)	1200 Tabs/Caps
Oxycodone/Asa	500 Tabs

[185] *See* Deposition of Craig Baranski, p. 82-83.

[186] *See* Deposition of Steve Reardon, p. 429.

(Percodan, Endodan, Roxiprin)

Oxycodone 600 Tabs[187]
(Oxycontin, Roxicodone)

During this timeframe, Steve Reardon, Vice President Quality and Regulatory Affairs, was in charge of the anti-diversion department at Cardinal Health. Mr. Reardon testified that this "Excessive Order" system was expected to be implemented uniformly across the whole company.[188] According to Mr. Reardon, Cardinal Health's policy was for any order that exceeded these "Excessive Order" postings in the cage to be reported to the DEA as a suspicious order **prior to shipment**.[189]

I asked SLCG to determine how many daily orders for customers in Cabell County and Huntington exceeded the daily limit set by Cardinal Health between 1996 to 2018 which resulted in the following:[190]

	Flagged Orders	**Flagged Dosage Units**
Oxycodone	47,440 (93.1% of all oxycodone orders)	16,527,880
Hydrocodone	37,183 (89.9% of all hydrocodone orders)	17,688,100

Furthermore, evidence in the record indicates that Cardinal Health employees instructed its personnel to ignore the daily limits. Cardinal Health's employee, Dave Strizzi, claims that these excess "charts" are for guidance and that orders should not be cut but that staff should "record the orders that exceed these limits for possible reporting to the DEA."[191] This is completely inconsistent with the way Cardinal Health's policy reads as well as the way Mr. Reardon explained it. Even more concerning, on November 1, 2006, Rafael Varela, one of Cardinal Health's QA & Compliance Managers, wrote, "the Vault Keyers were, until today, overriding the limiters for the vault items in the system… This is not supposed to happen without authorization."[192]

Even if the daily limit system was designed properly as a tool to identify suspicious orders, there is no evidence the system was sufficiently "operated." This concern was clear even to the

[187] CAH_MDL_PRIORPROD_DEA07_01383136, 01383401.

[188] *See* Reardon at 455 to 456.

[189] *See* Reardon at 453 to 456.

[190] McCann Report, App. 7.

[191] *See* CAH_MDL PRIORPROD_ DEA07_00319489.

[192] *See* CAH_MDL PRIORPROD_ DEA07_01052516.

employees at Cardinal Health. On December 5, 2007, just after the license suspension of Cardinal Health's Auburn distribution center, Bob Kurtz sent a follow-up email to Rafael Varela, one of Cardinal Health's Compliance and QA Managers, and explained the following related to Cardinal's "picker and checker" system:

> The manual process we perform now with the discovery of suspected excessive purchases being left up to the keyer notifying myself, or a picker/double checker/QCer questioning an amount being processed seems to **leave ample opportunity for failure**. A system generated "flag" would be a more complete or thorough method of determining spikes or excessive quantities than what we are currently performing.
>
> As you know, I've investigated many accounts, tracked their ordering history, and reached out for guidance and directions. But without "someone" bringing a suspected "excessive quantity" order to our attention, **many, many more could be going out the door under our noses. I wonder could a similar situation happen in Lakeland and management be questioned "why wasn't this discovered?**"[193]

In my opinion, this represents a breach of the security requirement as it applies to Cardinal Health.

This is all consistent with the testimony of Mark Hartman, who took over the regulatory department in December 2007, as the Senior Vice President of Supply Chain Integrity.[194] According to Mr. Hartman as well as a power point presentation that he prepared, Cardinal Health had leaks in its supply chain.[195] This is during the same time that Cardinal was addressing three Immediate Suspension Orders and one Order to Show Cause across four of its distribution centers related to Cardinal Health's failure to maintain effective controls against diversion.[196] Specifically, Cardinal Health was alleged to have been failing to comply with its regulatory duties and distributing excess oxycodone, which is consistent with my opinions for Policy Period #1.

Even Cardinal Health's counsel recognized that Cardinal Health did not have a sufficient SOMS to properly detect all suspicious orders during this timeframe.[197] Prior to and during portions of 2008, Cardinal Health was still delivering not only controlled substances, but oxycodone in particular, to suspected internet pharmacies after being specifically told that such an action would be illegal.[198] Further, a spreadsheet produced by Cardinal describes a number of

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[193] *See* CAH_MDL_PRIORPROD_DEA07_00135433 (emphasis added).

[194] *See* Deposition of Mark Hartman at 17:11-16.

[195] *See id*. 236: 5-13, *see also* Hartman Depo. Exhibit 13.

[196] CAH_MDL2804_00641449.

[197] *See* CAH_MDL_PRIORPROD_DEA07_00968964 ("[H]ere, you have an Inet Pharmacy, the account is open, and Cardinal does not yet have a system for detecting all suspicious orders.").

[198] *Id*.; *see also*, Schedule II, distributions to Ross Westbank (2006-2014).

pharmacies that Cardinal cut off prior to 2008 and the underlying reasons for termination.[199] This document shows that Cardinal serviced pharmacies whose purchase histories, ratio of purchases of controlled to non-controlled substances, ratio of cash for purchases of controlled substances, total volume of certain controlled substances (hydrocodone, oxycodone), and other factors indicated potential diversion. Had Cardinal investigated these pharmacies sooner, as it should have, Cardinal would have been aware of this activity.

b. Policy Period #2 (2008 to 2012):

i. **Thresholds**

After the DEA instituted an enforcement action against Cardinal Health, it was forced to begin implementing a different SOM system in 2008. Cardinal Health claims that this revised system focused on a dual approach. The first approach used in this system required the creation of a Threshold for each customer and that the Threshold be specific for each base code. The Threshold was designed to operate as a stop on any shipment which exceeded the predetermined Threshold.[200] The Second step in this process required Cardinal Health to be familiar with its customers (Know Your Customers). The record does not support that Cardinal Health complied with its own thresholds. To the contrary, Cardinal Health continued to ship orders that exceeded its own Thresholds without complying with their KYC requirements or conducting sufficient due diligence before shipping suspicious orders.

Cardinal Health's approach to setting these Thresholds for its customers, as with the ILR's, was fatally flawed. Cardinal Health's Threshold system required it to determine the 12 month average for its customers, for each base code based on type and size of customer, and multiply that average by a multiple of 3 for schedule II's and a multiple of 5 for schedule III's.[201] This too is insufficient under the security requirement because: (a) it premises setting a threshold limit in the middle of a national opioid epidemic;[202] and (b) Cardinal Health relies on the Reno Report[203] using a 3x and 5x multiple respectively, which, again, is recommended only to apply to extraordinary

[199] CAH_MDL2804_00664969.

[200] *See Deposition of Shirlene Justus,* July 13, 2018 at 86:14 to 88:6.

[201] CAH_MDL_PRIORPROD_AG_0000013.

[202] *See* Deposition of Mark Hartman, 286:5-11. Nicholas Rausch testified that Deloitte, Cardinal Health's consultant involved in designing Cardinal Health's initial threshold system, excluded pharmacies identified in the DEA's 2007/2008 Immediate Suspension Orders in calculating thresholds. Depo. of Rausch, 216:13-217:8. It is my opinion that excluding only those pharmacies from Cardinal Health and Deloitte's calculations was insufficient to capture the impact of the national epidemic.

[203] *See* Deposition of Jennifer Norris (Cardinal Health 30(b) Designee), 134:16-23 ("An ingredient limit report is the report that was required pursuant to the 1998 DEA report to, I believe, the Attorney General. It included the algorithm for certain pharmaceuticals, and we on a monthly basis provided the report of the customers who had exceeded the designated amount that you achieve pursuant to doing the algorithm, the math problem.").

size of controlled substances containing List 1 chemicals, and not to Schedule II and Schedule III controlled substances which do not contain List I chemicals.[204]

Cardinal Health's productions demonstrate that it regularly ignored the thresholds it had set for its customers. The DEA found that following the 2008 settlement with the DEA, Cardinal failed to report any suspicious orders of oxycodone products for pharmacies in Maryland between 2008 and October 1, 2011.[205] During this time, the DEA found that Cardinal Health increased thresholds for these Maryland pharmacies despite evidence indicating potential diversion.[206] This fact was also part of the 2012 DEA enforcement action based on Cardinal Health's Florida conduct. This conduct was further highlighted in the House Energy and Commerce Committee's December 19, 2018 report "Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia."[207] This appears to be a systemic problem that was occurring throughout Cardinal Health's nationwide operations. Documents provided by Cardinal Health related to the *Holder v. Cardinal Health* litigation demonstrate this point. The following are examples of the number of times customers were permitted to exceed their predetermined thresholds:

- CVS 219 allowed to exceed its threshold 14 out of 16 months.
- Gulf Coast allowed to exceed its threshold 12 out of 29 months.
- CVS 5195 allowed to exceed its threshold 5 consecutive months.
- Caremed allowed to exceed its threshold 13 out of 17 months.[208]

This conduct is concerning when viewed in light of the information not only available to Cardinal Health but that which their people actually reviewed and had knowledge of. The slide below was created by Cardinal to provide "talking points" for the "abnormal" buying pattern of CVS 219 in Sanford, Florida.[209]

[204] *See* Deposition of Steve Reardon, 432:8-433:3.

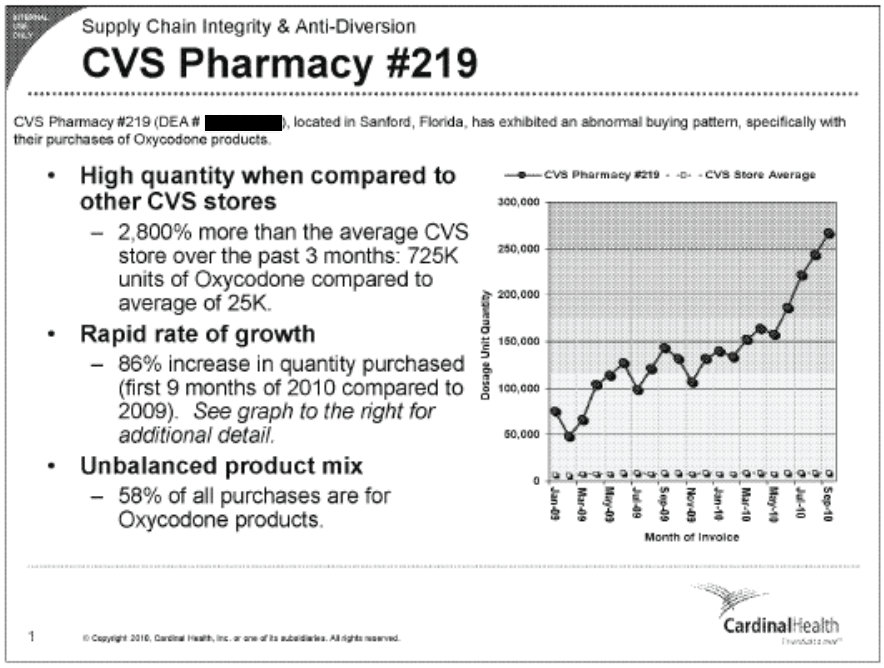
[205] CAH_MDL2804_02509732, 02509741.

[206] *Id*. at 02509756, 02509758, 02509764, 02509780

[207] *See* pp. 184-186.

[208] *See* CAH_MDL_PRIORPROD_DEA12_00004353; Depo. of Christopher Forst at 312:22-320:9.

[209] *See* CAH_MDL_PRIORPROD_DEA12_00003244, 00003250; CAH_MDL2804_01103874, 01103875; and CAH_MDL_PRIORPROD_DEA12_00014224 at 00014248 para 46.



Even Christopher Forst, who is a pharmacist and was Director of quality/regulatory affairs, testified that he "would be uncomfortable selling that much to the store," referring to CVS 219.[210]

As mentioned above this same practice of exceeding thresholds was not limited to the above Florida pharmacies but also is evident in Huntington and Cabell County. I have reviewed a spreadsheet produced by Cardinal as CAH_FEDWV_00001115, which contains information related to thresholds set by Cardinal for customers in Cabell County and Huntington. The spreadsheet contains the dates pharmacies exceeded their thresholds and what action was ultimately taken with respect to the orders (*e.g.*, Cut, Released, or Reported). Based on the due diligence files produced, Cardinal frequently failed to conduct adequate due diligence with respect to orders placed by customers in Huntington and Cabell County that exceeded their respective thresholds for controlled substances. The table below identifies a small sample of the orders that were ultimately released and allowed to ship despite there being inadequately documented due diligence supporting the justification indicated for the release.[211]

Date of Threshold Event	Pharmacy	Controlled Substance	Result	Justification (CAH_MDL2804_00001115)	Due Diligence

[210] *See* Deposition of Christopher Forst at 333:22-23.

[211] *See, e.g.*, CAH_FEDWV_00000001 - 00001109.

11/25/2010	T AND J Enterprises, Inc., dba The Medicine Shoppe 2402 Adams Avenue, Huntington, WV (DEA# [redacted])	DF# 9143 (Oxycodone Hydrochloride) OXYCONTIN 80MG 100 CR C2	Released	NOT UNREASONABLE QUANTITY, PATTERN, AND/OR FREQUENCY	None
11/27/2010	T AND J Enterprises, Inc., dba The Medicine Shoppe 2402 Adams Avenue, Huntington, WV (DEA# [redacted])	DF# 9143 (Oxycodone Hydrochloride) OXYCODONE HCL 30MG 100 IR C2	Released	NOT UNREASONABLE QUANTITY, PATTERN, AND/OR FREQUENCY	None
6/25/2012	West Virginia CVS Pharmacy, LLC (CVS# 3480) 5179 US Route 60 East, Huntington, WV (DEA# [redacted])	DF# 9143 (Oxycodone Hydrochloride) OXYCODONE/ APAP 10-650MG 100 C2	Released	"NOT UNREASONABLE QUANTITY, PATTERN, AND/OR FREQUENCY"	None
6/25/2012	West Virginia CVS Pharmacy, LLC (CVS# 3480) 5179 US Route 60 East, Huntington, WV (DEA# [redacted])	DF# 9143 (Oxycodone Hydrochloride) PERCOCET 10MG-325MG 100 C2	Released	"NOT UNREASONABLE QUANTITY, PATTERN, AND/OR FREQUENCY"	None

According to Christopher Forst, when an order is placed by a pharmacy or drug store that exceeds a predetermined threshold, the particular order is automatically stopped.[212] This means that the order would not be filled until it was reviewed by a Cardinal Health employee and **a conscious decision was made** to release the order that exceeded the threshold.[213]

By setting a threshold for its respective customers Cardinal Health internally determined at what level a specific order would be triggered as potentially suspicious. Such a trigger under Cardinal Health's system then implemented the KYC requirement and required Cardinal Health to conduct due diligence to determine whether the triggering order could be shipped or not. Such due diligence must be appropriately documented in the respective customers' due diligence files to insure an adequate history of investigative activity.

ii. **Know Your Customer**

The KYC aspect of Cardinal Health's system was devised in a way to allow for the documentary support of the regulatory decision Cardinal Health is required to make of its customers. This system was intended to collect information from several differing functions including but not limited to: (a) new account approval process, (b) on-sight investigations, (c) additional internal research conducted on the customer, and (d) justifications for changes made and due diligence conducted related to any specific order or threshold change.

Cardinal Health failures came not necessarily in the design of its KYC system but in the **execution** and **operation** of the system. Due diligence files should be complete, accurate, and maintained on each customer to allow a registrant to have a sufficient understanding of each specific customer. These customer files also must be accessible to allow a registrant to use this information when it receives an order that it believes is potentially suspicious. Based on the information that I have reviewed Cardinal did not maintain sufficient KYC/due diligence files on each of its customers to establish sufficient knowledge of the customers. The due diligence documents Cardinal identified were not organized in a manner that would allow them to be useful for future investigations.

Cardinal also separated its retail customers into two categories: (a) retail independents (RI) and (b) retail or national chains. During Policy Period #2, Cardinal treated retail chain customers differently from retail independents as it relates to KYC/due diligence. Cardinal Health relied on chain customers to conduct their own due diligence and investigations related to potential suspicious orders and diversion concerns.[214] This practice continued even after Cardinal Health was told by the DEA in November 2009 that Cardinal Health "must exercise the same level of

[212] *See* Deposition of Christopher Forst at 339: 9-24.

[213] *See id*.

[214] *See* Declaration of Michael A. Moné, CAH_MDL_PRIORPROD_DEA12_00014053 at page 13; CAH_MDL2804_03262274, 03262438.

oversight with respect to retail chain pharmacies and retail independent pharmacies."[215] The CSA does not permit a registrant to delegate or shift the burden of maintaining effective controls to a third party, even if that third party is also a registrant. These practices were not sufficient for Cardinal Health to meet its obligations under the security requirement.

c. Policy Period #3 (2012 to Present):

Cardinal Health's third redesign of its SOM program (2012-present) occurred after the second enforcement action by the DEA. Cardinal Health asserted that this system was less subjective but in reality, it was the contrary. The system that Cardinal implemented in 2013 continued to utilize both the threshold system and the KYC/due diligence component. However, Cardinal Health's revised system now based the thresholds solely on the individual customer's information without consideration for the population that it served or comparison to similar customers.[216] This violated Cardinal Health's own Standard Operating Procedures (SOP).[217]

Cardinal also developed working guidelines, or "General Work Instructions," that, according to Cardinal's VP of QRA, Supply Chain Integrity, Todd Cameron, are utilized more frequently by Cardinal and contain more "action oriented detail" than the Standard Operating Procedures.[218] One set of these guidelines describe a process for Cardinal to permit customers who have exceeded their threshold for a particular drug to receive a certain percentage of dosage units over the threshold once per accrual period per drug family.[219] The amount a customer was allowed to receive above its threshold depended on the current [redacted]

According to internal documents produced by Cardinal, it appears that Cardinal did not want its use of a "percentage over threshold" process to be disclosed to the DEA. In April 2014, Cardinal's Director of Investigations QRA, Ullrich Mayeski, tasked Cardinal employees Kim Howenstein and Kimberly Anna-Soisson to create a presentation for Mayeski to give to Cardinal Compliance Officers concerning how the Compliance Officers would "facilitate an overview conversation about the SOM program during a DEA Cyclic Inspection."[221] Ullrich also advised Howenstein and Anna-Soisson that the presentation would be shared with the DEA during an on-

[215] *See* Correcting Declaration of Michael A. Moné, CAH_MDL_PRIORPROD_DEA12_00013747 at page 4; Depo. of Steven Morse, 113:8-13; Depo. of Christopher Forst, 33:9-34:5.

[216] *See* Depo. of Todd Cameron, 54-69.

[217] CAH_MDL_PRIORPROD_AG_0028694.

[218] *See* Depo. of Todd Cameron, 118:2-119:5.

[219] CAH_MDL2804_00012244, 00012249-00012267.

[220] *Id*. at CAH_MDL2804_00012263-00012264.

[221] CAH_MDL2804_00012244.

site inspection.[222] Howenstein and Anna-Soisson developed a draft and in an email on May 1, 2014, discussing the document, Anna-Soisson stated that she "intentionally left out the part about releasing beyond the [threshold]" because she "did not want to draw attention to the practice but agree that the CO's should know it exists."[223] In an instant message exchange, Anna-Soisson then told Mayeski that she "did not want to draw attention to what I believe they would consider questionable at best so we agreed and put it in the notes only section. That way CO's know it occurs but it isn't so obvious."[224]Anna-Soisson had previously raised issues about this practice in an email to Todd Cameron and Christopher Forst, pointing out that analysts were permitted to release a percentage over threshold even in instances where a threshold increase was not warranted or where the customer was "failing" other objective tests.[225]

With the exception of one order from 2010, this is the first timeframe for which Cardinal Health has produced specific suspicious orders related to the City of Huntington and Cabell County, West Virginia. Cardinal Health identified 292 suspicious orders for Huntington and Cabell County combined from August 2012 to present.[226]

3. Cardinal Health failed to *report* suspicious orders of controlled substances in violation of the *reporting requirement* set forth in 21 C.F.R. § 1301.74(b).

Cardinal Health timely reported zero suspicious orders in the City of Huntington and Cabell County, West Virginia from 1996 to at least 2008, based on the records provided. The ILR is an after-the-fact distribution report which is insufficient. Cardinal has produced information related to 116 suspicious orders that were reported to the DEA for Huntington and Cabell County during Policy Period #2 (2008-2012), though nearly all were reported in the second half of 2012.[227] However, it was Cardinal Health's practice not to report suspicious orders but to "report an order as suspicious when the customer appeared suspicious" and Cardinal Health was going to terminate service to that customer.[228] Waiting to the point of termination of a customer before reporting any suspicious orders related to the customer is not sufficient to meet the reporting requirement. This conclusion is supported by several documents produced by Cardinal Health. First, Cardinal's November 1, 2012, Audit Committee Meeting packet indicates that during fiscal years 2010 and 2011 Cardinal only reported 30 and 47 suspicious orders, respectively, nationwide. This is in stark

[222] *Id.*

[223] CAH_MDL2804_00012953.

[224] CAH_MDL2804_02350970.

[225] CAH_MDL2804_00009412, 00009413.

[226] CAH_MDL2804_03468434.

[227] CAH_MDL2804_03468434.

[228] *See Investigation Report of the Special Demand Committee*, CAH_MDL_PRIORPROD_HOUSE_0003331 at page 36; *also see Supplemental Declaration of Michael A. Mone*, CAH_MDL_PRIORPROD_DEA12_00014762 at page 8; *also see* CAH_MDL2804_03262274, 03262438.

contrast to the 6,326% increase of reported suspicious orders that allegedly occurred in 2012, according to the document.[229] Additionally, during this same period the Baltimore DEA office provided a presentation to Cardinal Health that, among other things, outlined that between 2008 and October 1, 2011, Cardinal did not report any suspicious orders of oxycodone products in Maryland.[230]

Finally, during Policy Period #3 Cardinal Health reported 176 suspicious orders but continued to ship the same base codes to many of those customers.[231] Any additional orders from these customers without having been cleared would also constitute a suspicious order and should have been reported to the DEA as such.[232] Also during the 2012-2015 timeframe, Cardinal's employee testified that Cardinal failed to report to the DEA approximately 14,000 separate suspicious orders from around the country. According to Mr. Cameron these were for "subbase codes" which would generally be for more highly abused dosages.[233] Additionally, using any of the methodologies described in the Expert Report of Craig McCann, it is apparent Cardinal Health failed to report thousands of suspicious orders arising out the City of Huntington and Cabell County.[234]

4. Cardinal Health failed to *stop shipment* of suspicious orders of controlled substances in violation of the requirement to *maintain effective controls against diversion* as set forth in 21 U.S.C.A. § 823(b)(1) [1970].

Again, the premise of the CSA is to ensure that when dealing with these controlled substances that are highly addictive in nature and dangerous that we do so in a way that best protects our communities. This is signified in the CSA's requirement to all registrants' to "maintain effective controls" against diversion. With this understanding, even if Cardinal Health had properly identified suspicious orders, its corporate policy from 1996 to 2008 was to ship anyway. This is a blatant failure to maintain effective controls to prevent diversion and a breach of their regulatory obligations as a registrant.

Being that I have not specifically seen any suspicious orders identified by Cardinal Health as being reported for customers in Huntington and Cabell County during Policy Period #2, other than those reported the final months of 2012 and a single order from 2010, I cannot say whether Cardinal Health shipped any orders into Huntington and Cabell County that Cardinal Health

[229] CAH_MDL2804_03262274, 03262438.

[230] CAH_MDL2804_02509732, 02509741.

[231] *See* "Know Your Customer" section above; *also see* CAH_MDL2804_03468434.

[232] CAH_MDL2804_00227518, 587.

[233] Depo. of Todd Cameron, pp. 268-271.

[234] *See* Section III above.

identified as suspicious. However, I can say that Cardinal Health during this timeframe did ship suspicious orders that should have been identified.[235]

B. McKesson Corporation

Distribution Center: Washington Courthouse, OH

DEA Registrant Number: [redacted]

Transactional Data Disclosed: Date Range: 10/01/04 – 6/30/2018[236]

Cabell County/Huntington Volume: [237]

Oxycodone	3,983,350 dosage units
Hydrocodone	3,732,930 dosage units

1. Court Ordered SOMS Discovery Disclosures:

- *McKesson Corporation's Objections and Responses to Plaintiffs' First Combined Discovery Requests to Distributors (Nos. 1-11)* (November 29, 2019);

McKesson Corporation's Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests to Distributors (February 28, 2020)

- *McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests to Distributors* (March 17, 2020)
- *McKesson Corporation's Objections and Responses to Plaintiffs' Requests for Production* (March 30, 2020)
- *McKesson Corporation's Objections and Responses to Plaintiffs' Third Set of Combined Discovery Requests* (April 13, 2020)

2. SOMS Corporate Policy Disclosed:

McKesson Drug Operations Manual – Section 55 (January 15, 1997)[238]

McKesson Corporation (hereinafter "McKesson") utilized this system from at least 1997 to May 2007. Section 55 outlines five different reports concerning a customer's purchases (Controlled Substances Sales Report, Controlled Substances Customer Purchase Report, Daily

[235] *See* Section III above.

[236] MCKMDL01391112.

[237] McCann Report, App. 7.

[238] MCKMDL00651873.

Controlled Substance Suspicious Order Warning Report, Monthly Controlled Substance Suspicious Purchases Report and the Monthly ARCOS Customer Recap Variance).[239] However, the output from these reports was rather basic. McKesson created daily and monthly reports that documented retrospective sales of controlled substances, including opioids, when those sales exceeded three times of that customer's 12 month purchase average for that base code.[240] After it was generated, a hard copy of the report was mailed or faxed to the local DEA office. The reports that were generated were known as DU-45 reports. However, it should be noted that McKesson has not been able to locate any DU-45 reports that were allegedly generated from the Washington Courthouse Distribution Center.[241]

Lifestyle Drug Monitoring Program (May 2007)[242]

In May 2007, McKesson launched the Lifestyle Drug Monitoring Program (hereinafter "LDMP"). The LDMP was limited to four drug products (oxycodone, hydrocodone, alprazolam and phentermine).[243] For these four drugs, an 8,000 monthly dosage unit threshold was set for every customer nationwide.[244] Once the 8,000 dosage unit threshold was hit in a given month, a 3 level review process was to be triggered.[245] However, the LDMP had no mechanism to block orders once the 8,000 unit threshold was hit and an investigation was ongoing.[246] Therefore, despite the 8,000 unit threshold being hit by a particular customer, that customer was still permitted to place and receive orders for opioids, including oxycodone and hydrocodone.

Controlled Substances Monitoring Program (May 2008)[247]

In May 2008, McKesson launched the Controlled Substances Monitoring Program (hereinafter "CSMP"). The CSMP continued to apply monthly thresholds, however, under the CSMP monthly thresholds applied to all opioid products. Thresholds were initially set under the CSMP by reviewing the customer's 12 month purchase history for each base code, reviewing the highest month of purchases in that 12 month period, and adding a 10% buffer to that purchase

[239] MCKMDL00651873 at 00651919-20.

[240] MCKMDL00651873 at 00651919-20; 1/10/19 Gary Hilliard Depo. at 163:21-169:7.

[241] *McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests to Distributors* at pp. 9-10.

[242] MCKMDL00355251.

[243] MCKMDL00355251.

[244] MCKMDL00355251.

[245] MCKMDL00355251 at MCKMDL00355252-00355255.

[246] 11/28/18 William Mahoney Depo. at 584:11-17.

[247] MCKMDL00518064.

amount.[248] Thresholds could then be adjusted thereafter through a process referred to as a threshold change request (hereinafter "TCR").[249] In 2015, McKesson supplemented the CSMP by adding an analysis of certain statistical and non-statistical red flags.[250] Beginning in 2017 and extending into 2018 McKesson began implementing a threshold system developed by Analysis Group (hereinafter "AGI").[251] This system allowed for the establishment of thresholds using several different methodologies including one based on the same customer's prior orders, another based on purchases from similarly situated customer's in the same geographic region, and others using custom methodologies developed by McKesson's regulatory team.[252]

3. **Enforcement Actions**

a. On August 4, 2006, DEA issued an Order to Show Cause with respect to McKesson's Lakeland distribution center for failing to maintain effective controls against diversion concerning opioid products. [253]

b. On November 1, 2007, DEA issued an Order to Show Cause against McKesson's Landover distribution center for failing to maintain effective controls against diversion concerning opioid products.[254]

c. On May 2, 2008, McKesson and DOJ entered into a settlement agreement wherein McKesson agreed to pay a $13.25 million dollar fine and agreed to make improvements to its controlled substances monitoring practices. The settlement involved allegations by DOJ that McKesson failed to maintain effective controls against diversion at six of its distribution centers.[255]

d. On January 5, 2017, McKesson entered into a settlement agreement wherein it agreed to pay a $150 million civil penalty for violation of the 2008 settlement agreement as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West

[248] MCKMDL00267635 at MCKMDL00267641; MCKMDL00633917.

[249] MCKMDL00267635 at 00267649; MCKMDL00518064 at MCKMDL00518064, 67.

[250] MCKMDL00330099 at MCKMDL0033114, MCKMDL0033122-23.

[251] MCKMDL00437057.

[252] MCKMDL00437057 at 00437059-60.

[253] MCKMDL00337001.

[254] MCKMDL00337001.

[255] MCKMDL00337001 at 00337013-15.

Sacramento, California.[256] Moreover, as part of this settlement agreement McKesson accepted responsibility for failing to identify and report suspicious orders following the 2008 settlement agreement.[257]

4. **Suspicious Orders Reported in the City of Huntington and Cabell County, West Virginia Jurisdictions**[258]

	Pre-Shipment Reporting	Post-Shipment Reporting
1996	0	
1997	0[259]	DU-45 Reports
1998	0	DU-45 Reports
1999	0	DU-45 Reports
2000	0	DU-45 Reports
2001	0	DU-45 Reports
2002	0	DU-45 Reports
2003	0	DU-45 Reports
2004	0	DU-45 Reports
2005	0	DU-45 Reports
2006	0	DU-45 Reports
2007	0	DU-45 Reports
2008	0	
2009	0	
2010	0	
2011	0	
2012	0	
2013	5[260]	
2014	29	
2015	20	
2016	10	

[256] MCKMDL00355349 at 00355352-57.

[257] MCKMDL00355349 at 00355352.

[258] MCKMDL01391127.

[259] From 1997 through May 2007 it is possible that McKesson reported excessive orders by way of the DU-45 Report for pharmacies in Cabell County, however, as noted above none of those reports could be located by McKesson for the Distribution Center servicing Cabell County and McKesson's own employees have not viewed these reports as encompassing true suspicious orders. (*See* Gary Hilliard, Jan. 10, 2019 Deposition at 176:8-176:22; MCKMDL00510747). These reports solely listed shipments that had already occurred and did not report any orders pre-shipment.

[260] MCKMDL01391127. All of the suspicious order reports in 2013 occurred on or after August 1, 2013. The orders reported from 2013-2018 were orders blocked by McKesson and not shipped unless a TCR was subsequently approved.

2017	2	
2018	13[261]	

5. **Due Diligence Conducted**

From at least 1997 to May 2007, there was no due diligence conducted by McKesson regarding potential suspicious orders of controlled substances. From May 2007 to May 2008, McKesson represented to DOJ that under the LDMP "customers will not be allowed to exceed the 8,000 monthly dosage limit until a due diligence review has been completed."[262] However, this is not how the program appears to have actually operated, and in fact, documentation indicates that customers were routinely permitted to exceed the 8,000 monthly dosage thresholds prior to a due diligence review being completed by McKesson.[263] Both the LDMP and CSMP had a tiered three-level review process that was triggered once a customer met its monthly threshold. However, I have reviewed the due diligence files produced for Huntington and Cabell County covering the time span of 2006 to January, 1, 2014, and found no evidence of a Level 2 or Level 3 review being conducted prior to January 1, 2014.[264] Under the CSMP, McKesson also included a Know Your Customer Process. Again, however, McKesson's due diligence files produced in this case show that for years this process was very rudimentary and that very few substantive investigations were performed.[265] In 2015, McKesson began investigating specific statistical and non-statistical red flags.[266] However, each of the red flags included beginning in this time frame should have been monitored by McKesson for many years prior. McKesson's failure to do so serves as additional evidence of its failure to perform due diligence in preventing the diversion of opioid products.

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by McKesson has generally been substandard, at best. McKesson conducted no due diligence until 2007. Once a due diligence program was finally instituted to require a review before a customer's opioid dosage unit threshold could be increased, threshold increases were routinely authorized with little to no justification. Also, as McKesson regularly showed complete deference to threshold increase requests from chain pharmacies, the

[261] The data I have reviewed runs through December 31, 2018 presently.

[262] MCKMDL00330924 at 00330926; also stamped MCK-HOI-002-0000001 at 0000003.

[263] *See e.g.*, MCKMDL00540033.

[264] MCKMDL01581299; MCKMDL00361092-MCKMDL00361103; MCKMDL00356945-MCKMDL00356992; MCKMDL00368075-MCKMDL00368093; MCKMDL00358572-MCKMDL00358624; MCKMDL0035741-MCKMDL00359817; MCKMDL00368103-MCKMDL00368105; MCKMDL00359956-MCKMDL00359978; MCKMDL00357132-MCKMDL00357219; MCKMDL00365652-MCKMDL00365836; MCKMDL00359877-MCKMDL00359015; MCKMDL00360871-MCKMDL00360890.

[265] *Id.*

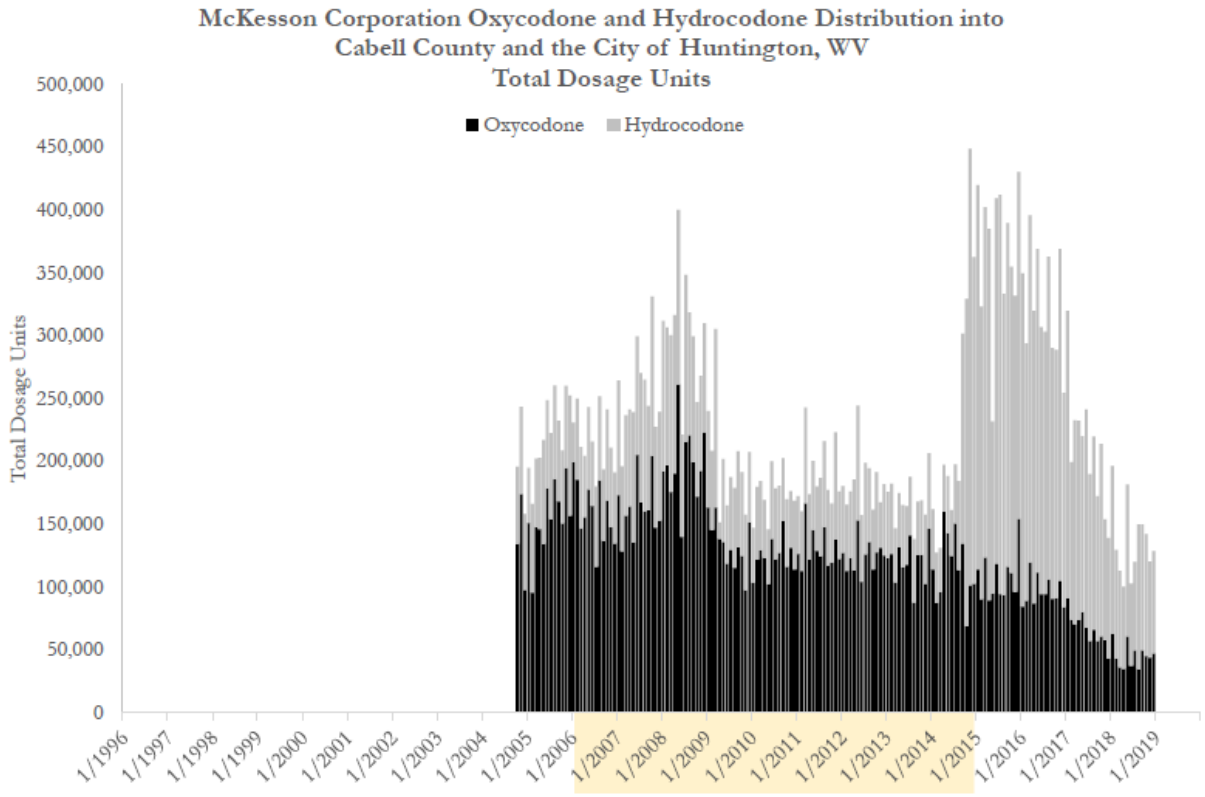
[266] MCKMDL00330099 at 00330118-120, 126-130.

due diligence for those customers was consistently lacking. Therefore, while McKesson has had some sort of due diligence program in place since 2007, a review of those programs in practice makes clear that for all practical purposes, McKesson's due diligence efforts have fallen short of what is required.

6. **Opinions Related to McKesson Corporation:**

McKesson Corporation failed to ***maintain effective controls*** against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970]. The graphs below demonstrate a clear escalation of prescription oxycodone and hydrocodone by McKesson into Huntington and Cabell County by dose, base weight, and MME.[267]

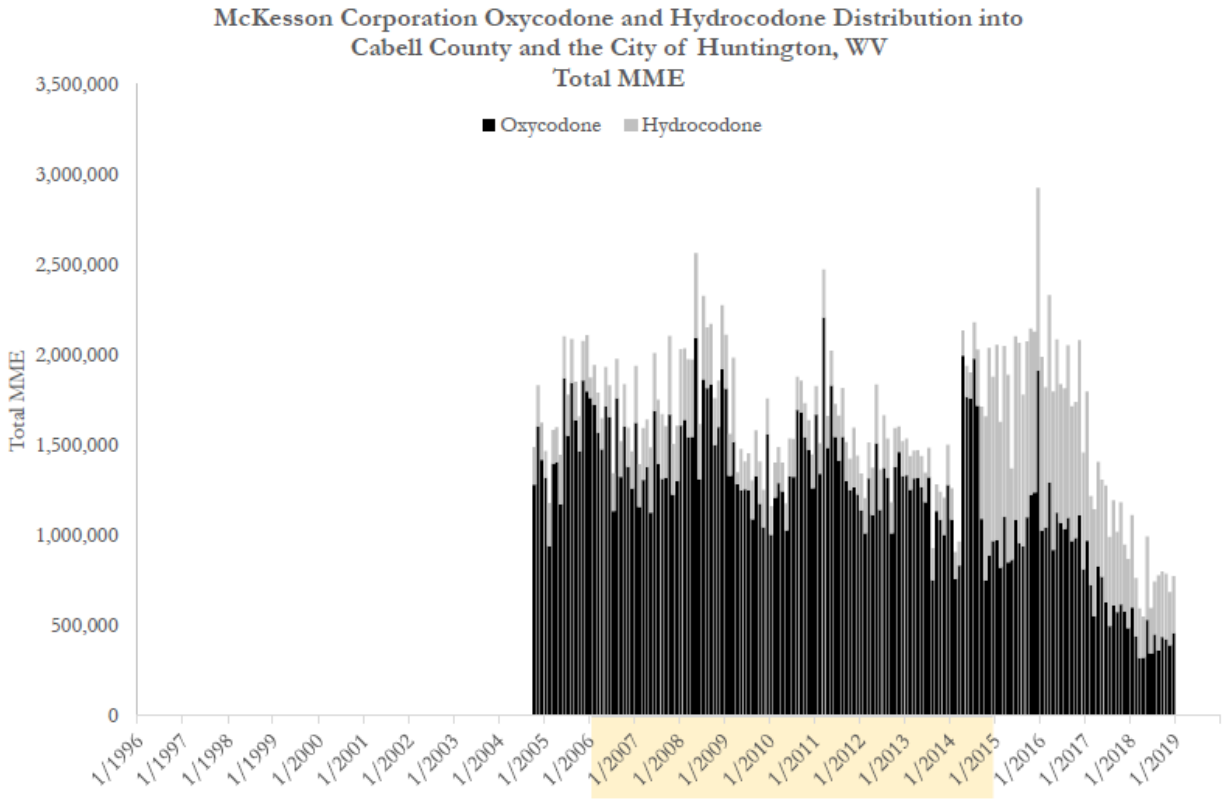
Region: Cabell County and the City of Huntington, WV
Time: 10/2004 - 12/2018
Seller: McKesson Corporation
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (McKesson 10/2004-12/2018)

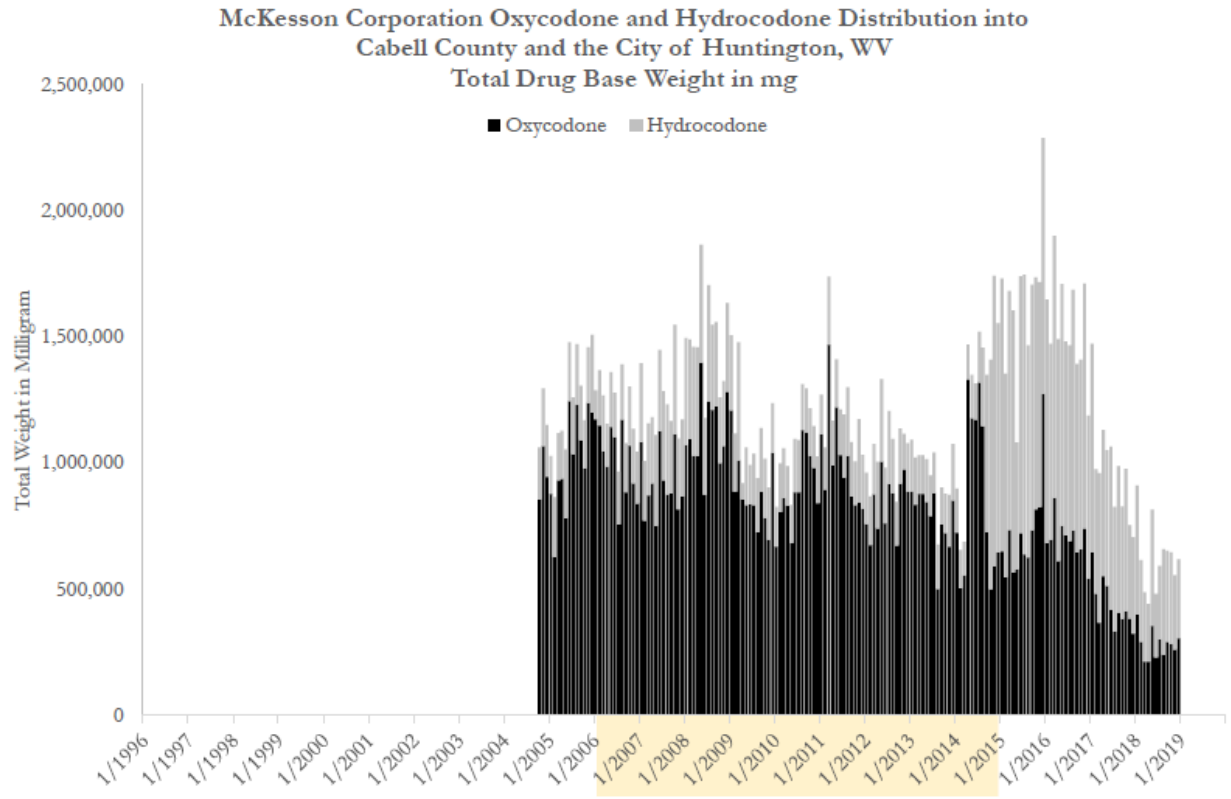
[267] McCann Report, App. 9(C).

Region: Cabell County and the City of Huntington, WV
Time: 10/2004 - 12/2018
Seller: McKesson Corporation
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (McKesson 10/2004-12/2018)

Region: Cabell County and the City of Huntington, WV
Time: 10/2004 - 12/2018
Seller: McKesson Corporation
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (McKesson 10/2004-12/2018)

The most effective control to prevent diversion is blocking a suspicious order before it is shipped. This notion is consistent with DEA guidance that has been provided to industry for decades, including guidance provided directly from DEA to McKesson as early as 1993.[268] As discussed above, from at least 1997 to May 2008, McKesson had no controls in place to block suspicious orders before they were shipped. Thus, any controls that were in place during this time period were completely ineffective in meeting the ultimate goal - the prevention of diversion.

With the launch of the CSMP in May 2008, for the first time McKesson established a process for blocking orders that were identified as suspicious. However, it is clear that from the time the CSMP was launched that McKesson's programs contained multiple loopholes to ensure as few orders as possible were blocked, thereby ensuring that the controls that were put in place remained completely ineffective. In fact, at the outset of the program McKesson notified all of its customers they should not expect any change in their ability to order controlled substances under

[268] (*See e.g.*, 1996 DEA Investigators Manual (CAH_MDL2804_02203346); DEA Memorandum, Legal Guidance on Reporting Suspicious Orders (March 1, 2007) (CAH_MDL_PRIORPROD_DEA12_00000609); US-DEA-00026154.

the CSMP. In a document that was to be shared with McKesson's pharmacy customers when introducing them to the CSMP, McKesson stated "[t]his program addresses the DEA's requirements to ensure controlled substances are used in the way they were intended, but it also ensures that you as a McKesson customer can continue with **business as usual**."[269] Given that this document was written just after McKesson entered into a $13.25 million dollar settlement with DOJ for failing to have effective controls against diversion as it pertained to opioid distribution, the message to McKesson's customers should have been that it would be anything but business as usual for them. However, unfortunately, this mentality appears to have been pervasive within McKesson's regulatory department for years to come, contributing to the following significant shortcomings with its SOM programs.

First, while McKesson established thresholds under the CSMP, those thresholds were frequently set far too high to ever be triggered. In fact, in August 2014, DOJ pointed out this fatal flaw in McKesson's CSMP. DOJ noted that McKesson's review process under the CSMP was not even triggered until a customer purchased more than 10% of their average[270] ordering month in the prior 12-month period. Not to mention, these thresholds were set based on purchases from 2007-2008 which DOJ noted was a "year in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies."[271] The extremely high thresholds set by McKesson for controlled substances did not go unnoticed within the company. On August 31, 2011, Director of Regulatory Affairs, David Gustin, noted "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases.'"[272] Despite Mr. Gustin's concerns, no serious efforts were undertaken to systematically reduce thresholds until 2015, a full four years later.[273] McKesson also continued to utilize a form of this system to set new thresholds until switching to the AGI based threshold algorithm in the 2017-2018 time period. In fact, the "business as usual" mentality noted above continued even after McKesson entered into a $150 million settlement with DOJ for its continuing failure to have effective controls against diversion following the 2008 settlement. Only two weeks after the settlement agreement was signed, McKesson's Senior Director of Regulatory Affairs, Nate Hartle,

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[269] MCKMDL00543610 at 00543613 (emphasis added).

[270] The reference to the thresholds being set based on the average orders from the prior 12 months also underestimates how McKesson actually set thresholds. According to McKesson's own documents, these thresholds were set based on the highest ordering month from the prior 12 months, not the average month. (*See e.g.*, MCKMDL00626898; MCKMDL00633917).

[271] MCKMDL00409224 at 00409234.

[272] MCKMDL00507799.

[273] *See* MCKMDL00410744; MCKMDL00402184.

attempted to calm customer concerns that McKesson would be stricter on its supply of controlled substances by once again noting it would be "**business as usual from a threshold perspective**."[274]

Second, McKesson routinely increased thresholds without requiring adequate justification for the increases. In order to have a threshold increased under the CSMP, a customer was supposed to provide documentation supporting a legitimate change in business that warranted the threshold increase.[275] However, these requirements were routinely ignored. As an example, in April 2011, Director of Regulatory Affairs, David Gustin, expressed that McKesson needed to tighten up the process regarding threshold increases because threshold increases were "almost automatic" and being granted for insufficient reasons, like "business increase".[276] Regulatory Affairs Director Tom McDonald reiterated these concerns in July 2012. Mr. McDonald noted that the company was too liberally granting threshold increases without proper documentation and often based only a stated claim of business growth by the customer.[277] Mr. Gustin became so concerned about the lack of due diligence being conducted by McKesson that he even noted to other colleagues in regulatory affairs that "[w]e as DRAs need to get out visiting more customers and away from our laptops or the company is going to end up paying the price . . . big time."[278] [279] Another Regulatory Affairs Director, Michael Oriente, responded, "I am overwhelmed. I feel that I am going down a river without a paddle and fighting the rapids. Sooner or later, hopefully later I feel we will be burned by a customer that did not get enough due diligence. I feel it is more of when than if we have a problem rise up."[280] McKesson ultimately acknowledged the problem of deficient due diligence, especially as to threshold increase requests. A November 2013 training deck noted a desire to make threshold change increases "the exception, not the rule" going forward in order to address the lack of due diligence that had become the norm at McKesson related to threshold increase requests.[281] The lack of due diligence surrounding threshold increases was also apparent to DOJ. In August 2014, DOJ noted that McKesson appeared to be willing to approve threshold increases for opioids for the flimsiest of reasons.[282]

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[274] MCKMDL00418094 (emphasis added).

[275] MCKMDL00518064, 067.

[276] MCKMDL00507221 at 00507223.

[277] MCKMDL00633455.

[278] MCKMDL00634329 at 00634331.

[279] Mr. Gustin recently entered a plea agreement to the criminal offense of knowingly failing to file suspicious order reports related to his time spent as a Director of Regulatory Affairs for McKesson. *See* David B. Gustin Plea Agreement, 6:20-cr-00038-REW-HAI, Doc. # 7.

[280] MCKMDL00634329 at 00634330-31.

[281] MCKMDL00516748 at 00516754.

[282] MCKMDL00409224 at 00409235.

An example of McKesson's overall poor due diligence and its willingness to increase thresholds without proper due diligence can be found by analyzing Medicine Cabinet #5 (also referred to at times as Custom Script Pharmacy), was onboarded as a customer by McKesson on July 29, 2010.[283] On or about May 11, 2013, Medicine Cabinet #5 moved to 3436 U.S. Route 60 East, Barboursville, West Virginia. On October 7, 2010, this pharmacy sought a threshold increase for oxycodone from 23,500 doses per month to 30,500 doses per month.[284] The rationale for the proposed increase offered by the customer was the customer's plan to aggressively market for business from clinics that the pharmacy expected would result in a "25% surge in usage of product containing oxycodone."[285] No further justification was provided and I have seen no evidence supporting that any additional investigation was conducted by McKesson as to the basis for the request, including the suspicious nature of the request only relating to oxycodone containing products. The threshold increase requested was approved by McKesson on October 8, 2010, which was only 1 day after the request was made.[286] A further review revealed there were numerous oxycodone threshold increases for Medicine Cabinet on the following dates:

- July 29, 2010 – initial threshold of 8,000 dosage units
- August 10, 2010 – threshold increased to 16,000 dosage units
- September 17, 2010 – threshold increased to 23,500 dosage units
- October 8, 2010 – threshold increased to 30,500 dosage units

Data collected later by McKesson ultimately indicated that this pharmacy was almost exclusively purchasing controlled substances from McKesson with control/RX ratios for the months following the above noted threshold increase topping out consistently at 94%-98%.[287] ARCOS data further indicates that Custom Script Pharmacy was purchasing oxycodone from additional distributors.[288] I have seen no information in the diligence files for this pharmacy indicating that McKesson considered that it was not the only distributor supplying oxycodone to Custom Script Pharmacy in assessing the thresholds it set for this pharmacy or in determining whether to continue to supply oxycodone to this pharmacy. Transactional data also indicates that the oxycodone purchases for Custom Script Pharmacy were predominantly for the 30mg dosage strength, which is another red flag which should have been investigated.[289] However, I have seen no evidence that McKesson actually undertook an investigation along those lines.

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[283] MCKMDL00328705.

[284] MCKSTCT00137351.

[285] *Id.*

[286] MCKMDL00328705.

[287] MCKMDL00326665.

[288] McCann Report, App. 9(H).

[289] McCann report, App. 9(J).

There were significant red flags that should have been identified by McKesson to maintain effective controls to prevent diversion. The due diligence documents I have reviewed for Custom Script reflect that McKesson did not conduct adequate due diligence for this pharmacy.[290]

As a result of the October 2010 oxycodone threshold increase, Custom Script Pharmacy was permitted to order oxycodone in amounts that significantly exceeded the West Virginia and national averages for oxycodone for McKesson customers.[291]

The information available to McKesson revealed the Medicine Cabinet #5 (Custom Script Pharmacy) was owned by the same individual who owned the Sav-Rite No.1 (also later know as Medicine Cabinet #8 located in Kermit, West Virginia.[292] The report of the Energy and Commerce Committee of the U.S. House of Representatives related to the suspicious ordering of opioids by pharmacies located in West Virginia features this pharmacy prominently. The committee reviewed McKesson's conduct related to the distribution of opioids and compliance activities involving Sav-Rite No. 1. The report contained an extensive review of McKesson and the statements below detail some of the committee's findings:

- In 2006 and 2007, McKesson distributed more than 5.54 million dosages of hydrocodone and more than 204,000 dosages of oxycodone to Sav-Rite No. 1, population 406, in Kermit, West Virginia. The hydrocodone and oxycodone distributions McKesson made in 2006 and 2007 alone were enough that Sav-Rite No. 1 ranked as the company's third largest West Virginia purchaser of those two drugs between all of 2006 and 2017. In 2006, Sav-Rite No. 1 was ranked 22nd in the nation in regard to the overall number of hydrocodone pills it received.[293]

- Notably, and as discussed previously, the entirety of the due diligence file that McKesson produced to the Committee on Sav-Rite No. 1 contained only a single, two-page document—a November 2007 affidavit of James Wooley. The due diligence file did not include any documents regarding the level 1 review or the 8,000 dosage per month threshold imposed by the LDMP. The due diligence file also did not include any threshold event documentation indicating that Sav-Rite No. 1 surpassed the threshold, or any documents indicating that the threshold was raised above the 8,000 dosage per month threshold. Based on the documents provided, the Committee also cannot confirm the November 14, 2007, site visit by McKesson to

[290] MCKMDL00364908; MCKMDL01861247; MCKMDL01864197; MCKSTCT00120458; MCKMDL00326665; MCKMDL00328669; MCKMDL00328705; MCKMSTCT00128356; MCKSTCT00137351; MCKMDL00364912.

[291] McCann report, App. 9J.

[292] MCKMDL00364908 at MCKMDL00364912.

[293] United States, Congress, House, Committee on Energy and Commerce. *Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, December 19, 2018, p. 224.

Sav-Rite No. 1, or the reasons for the termination of the pharmacy by McKesson in November 2007.[294]

Third, McKesson has a long track record of absolute deference to retail national account customers when it comes to threshold increases. McKesson's Senior Director of Distribution Operations, Donald Walker, testified that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances.[295] Dispensing data was not requested or obtained from these RNA customers despite the fact that McKesson was aware that it was not the primary controlled substance distributor for these customers.[296] These practices resulted in McKesson routinely granting threshold increases to retail national account customers without any apparent due diligence including pharmacies in Cabell County.[297] McKesson's conduct in this regard was patently improper, as the duty to conduct due diligence is non-delegable. McKesson was also on notice based on publicly available information that Rite Aid itself had a poor track record of compliance with the CSA, which should have further dissuaded McKesson from delegating its statutory responsibilities to Rite Aid.[298] The impropriety of this conduct is also evidenced by the fact that McKesson was keenly aware that RNAs would become a target for diversionary activity in the late 2000s as a heightened focus was placed on independent stores.[299]

McKesson's deference to its retail national account customers is exemplified in its dealings with its Rite Aid customers across the country, including Cabell County. As described by Ed Bissler, manager of the Rite Aid account for McKesson from 1998 to 2010, Rite Aid was one of McKesson's largest customers and was its single largest customer for an extended period of time.[300] Almost immediately after the CSMP was enacted in 2008, Rite Aid asked to be opted out of the program or to have the program modified just for Rite Aid to ensure its supply of controlled substances would not be impacted.[301] While McKesson did not opt Rite Aid entirely out of the CSMP, it did modify the program for Rite Aid in multiple ways which resulted in a deficient

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[294] *Id*. at 226-227.

[295] *See* Donald Walker Deposition; Jan 10, 2019; pp. 190-193; *See also* MCKMDL01513753; MCKMDL01509848.

[296] *See e.g.*, MCKMDL02065947.

[297] *See e.g.*, MCKMDL00632877; MCKMDL01391128; MCKMDL00000497 at 00000520.

[298] *See* https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations; https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act.

[299] MCKMDL00735713.

[300] Ed Bissler Deposition; August 9, 2019, pp. 12-16.

[301] MCKMDL00632483 at 00632484.

monitoring of Rite Aid's controlled substance purchases. McKesson started by providing Rite Aid with a 30% buffer on its thresholds for all controlled substances, rather than the standard 10% buffer provided to other customers.[302]

Additionally, McKesson offered Rite Aid stores automatic threshold increases for schedule II controlled substances and schedule III controlled substances, including opioids. This started with 50% unilateral increases for Rite Aid on all schedule II products, including opioids.[303] Soon thereafter, these automatic increases were also granted specifically for hydrocodone products.[304] Further, McKesson provided daily threshold reports to Rite Aid and completely deferred to Rite Aid's corporate headquarters to dictate when thresholds should be increased.[305] In doing so, McKesson often ignored significant red flags of potential diversion.[306] A significant example of McKesson's historical lack of due diligence as to Rite Aid stores is also found in a McKesson investigation in 2016 that was prompted by a DEA subpoena. In September 2016, DEA subpoenaed due diligence files for 36 Rite Aid stores.[307] Of the 36 stores at issue, McKesson was only able to locate due diligence files for 3 of them.[308] The lack of due diligence for RNA customers was also confirmed in an April 2011 email which referenced that regulatory contacts for RNA customers were outdated for most RNA customers and non-existent for many others.[309]

Through these deferential practices, Rite Aid's opioid thresholds rose to excessively high levels. For example, in 2016 McKesson reduced the hydrocodone thresholds for Rite Aid by more than 24 million doses per month.[310] Unfortunately, by this point Rite Aid's thresholds had been excessively high for nearly 8 years. After accounting for the hydrocodone and oxycodone distributed to Rite Aid by McKesson and by Rite Aid itself [311], Rite Aid stores in Cabell County received large quantities of hydrocodone and oxycodone without any meaningful due diligence

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[302] MCKMDL00627168 at 00627170-71.

[303] MCKMDL00543795; *See e.g.,* MCKMDL00628036; MCKMDL00781102 at 00781120; MCKMDL00627955; MCKMDL00628187; MCKSTCT00059013.

[304] *See e.g.,* MCKMDL00628110; MCKMDL00781102 at 00781146, 00781149, & 00781155; MCKMDL00628025; MCKMDL00628047.

[305] *See, e.g.,* MCKMDL00632438.

[306] *See e.g.*, MCKMDL00631897; MCKMDL00781102 at 00781103, 00781144, 00781160, & 00781174.

[307] MCKMDL00441794.

[308] *Id.*

[309] MCKMDL01940951.

[310] MCKMDL00340143.

[311] McKesson also voluntarily chose not to even question Rite Aid concerning the amount of opioids, namely hydrocodone, it was distributing to its own stores. (Deposition of Michael Oriente, Sep. 6, 2019 at pp. 267-269).

being conducted by McKesson to support the propriety of the pills it distributed to these Rite Aid stores.[312]

Fourth, McKesson took affirmative steps to reduce the number of controlled substance orders it would have to block by warning customers that they were approaching a threshold, so the customer could seek an increase before McKesson would be forced to block their orders. In fact, this threshold warning system was designed solely to ensure that thresholds could be increased before any sales were lost. In discussing the creation of these reports in October 2006 Sharon Mackarness of McKesson stated, "[w]e are in the business to sell product. If we could produce a report … that warned a customers approach to the threshold, say at 85% of their 10,000 dosages, work could begin on justifying an increase in threshold prior to any lost sales."[313] These threshold warning reports were utilized for years thereafter to great effect as a preemptive tool to increase thresholds before orders had to be blocked. Presumably understanding the impropriety of providing these warning reports to customers, in November 2013 McKesson announced to its employees a new policy pertaining to threshold warning reports. The presentation states "[w]e are not communicating specific thresholds or providing threshold warning reports. We believe this is a better practice. Thresholds are not intended to allow customers to manage against a number. We strongly believe that customers should exercise their corresponding responsibility one prescription at a time."[314] The shift to not providing these warning reports was proper and McKesson should have abided by this policy without exception.

The above measures individually and collectively served to render McKesson's various programs ineffective as anti-diversion tools.

I have reviewed multiple internal audits conducted by McKesson which confirmed that the CSMP was not being implemented by McKesson in a way that it could be effective to prevent diversion of controlled substances. In August 2008, several months after the CSMP was launched, McKesson conducted an audit to assess the "effectiveness of CSMP policies, procedures, and controls."[315] Among the significant issues uncovered in this audit included:

- 1,359 customers that had not been assigned a threshold such that those customers could order unlimited amounts of controlled substances;[316]
- Level 1 reviews were not being consistently performed;[317]

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[312] *See e.g.,* Opioid Shipments from 2006-2014 for Rite Aid #968, McCann Report, App. 9H; Opioid Shipments from 2006-2014 for Rite Aid #3311, McCann Report, App. 9H; Opioid Shipments from 2006-2014 for Rite Aid #3423, McCann Report, App. 9H.

[313] MCKMDL00543971 at 00543972.

[314] MCKMDL00476786 at 00476791.

[315] MCKMDL00721376 at 00721379.

[316] MCKMDL00721376 at 00721380.

[317] MCKMDL00721376 at 00721380.

- Threshold change request forms were frequently not completed and when they were completed they were often not completed correctly;[318]
- The CSMP was unclear on when level II or level III investigations should occur or who should report suspicious orders.[319]
- Sales questionnaires and other diligence materials were not being routinely created and/or retained.[320]

Future audits confirmed that many of these problems persisted for years to come. In 2011, McKesson conducted an internal audit of four distribution centers, including the distribution center in Washington Courthouse, Ohio which has serviced Cabell County and surrounding areas. Numerous deficiencies were noted in the audit, which prompted Donald Walker to state, "I am certain that if we picked four different DC's we would find the same issues so we should assume this is a network-wide concern."[321] Issues outlined in the audit report that are particularly relevant here are as follows:

- Level 1 forms were routinely not completed including for Washington Courthouse which lacked level 1 forms for all omits in July 2010 and November 2010, the two months examined;[322]
- Threshold change request forms were frequently not completed.[323]

In November 2012, McKesson again conducted an internal audit as to the processes and procedures outlined in the CSMP. While McKesson concluded that the audit produced satisfactory results, some of the findings remained troubling.[324] Specifically, the audit report noted the following:

- A complete lack of customer questionnaires or level 1 review forms for retail national account customers;[325]

[318] MCKMDL00721376 at 00721383.

[319] MCKMDL00721376 at 00721384-85. (I have not found evidence that following this audit more detail was provided to assist a regulatory employee in understanding when a level II or level III review should be conducted.)

[320] MCKMDL00721376 at 007211386.

[321] MCKMDL00498057.

[322] MCKMDL00498057 at 00498069-70.

[323] MCKMDL00498057 at MCKMDL00498070-71.

[324] MCKMDL00721366 at 00721369.

[325] MCKMDL00721366 at 00721372; (*See also* MCKMDL00827928 and MCKMDL01940693, which further confirm the lack of compliance with due diligence responsibilities as to RNA accounts).

- Level 1 reviews not consistently being completed for other McKesson customers;[326]
- Monthly threshold change request and level 1 review self-audits were not being performed;[327]
- Documentation supporting some threshold change requests did not exist.[328]

As noted above, in May 2015, McKesson incorporated a list of statistical and non-statistical red flags into the CSMP.[329] However, all of these red flags included are concepts McKesson should have been monitoring for decades. For example, as part of this newly created red flag analysis, McKesson set out to monitor a "customer's controls/RX ratio, when compared to similar customers serviced by the same distribution center". [330] However, McKesson had specifically been told to monitor for exactly that type of information by DEA as far back as 2005.[331] Similarly, in 2015 McKesson began analyzing customer purchases against the "mean for the customer's servicing distribution center."[332] However, this sort of geographic analysis had been encouraged by the DEA at least since 1996.[333]

McKesson has recently adopted a new threshold system developed by AGI. While it is too soon to determine if that program will be effective in preventing diversion, there is reason to be concerned that it is flawed as well. Both the benchmark and same customer thresholds are premised on historical opioid sales levels for McKesson customers. That foundational construct is illogical given that it is the sales of opioids at these levels that has created the opioid epidemic and have resulted in McKesson paying significant fines for failing to maintain effective controls against diversion in 2008 and 2017.

An additional audit conducted by an Independent Review Organization ("IRO") as required by McKesson's 2017 settlement with DEA also noted several continued deficiencies in McKesson's compliance activities. While noting that it had limited visibility into the CSMP[334], the IRO did list the following concerns about the CSMP based on what it could observe:

[326] MCKMDL00721366 at 00721373.

[327] MCKMDL00721366 at 00721374-75.

[328] MCKMDL00721366 at 00721375.

[329] MCKMDL00330099 at 00330126-130.

[330] MCKMDL00330099 at 00330129.

[331] *See* MCKMDL00496859 at 00496862.

[332] MCKMDL00330099 at 00330129.

[333] *See* CAH_MDL2804_02203353 at 02203357.

[334] MCKMDL00450972 at 00450977.

- Regulatory affairs personnel needed to better justify their decision-making process related to threshold change requests and modifications of thresholds;[335]
- Documents supporting threshold change request decisions were routinely not included within the customers' files;[336]
- Some investigative reports did not adequately explain the resolution of red flags and others were "threadbare".[337]

McKesson Corporation failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the ***security requirement*** set forth in 21 C.F.R. § 1301.74(b).

a. **Policy Period #1 (1997-May 2007)**

Like Cardinal Health, McKesson claims the system it utilized from 1997 to May 2007 was premised upon guidance from the DEA. As previously noted, no guidance to justify McKesson's actions during this time period has ever been provided by the DEA. Nor does the record reveal any document which supports this contention. In fact, DEA correspondence from December 1993 actually supports the contrary conclusion. In a letter drafted by DEA's Director at the Office of Diversion Control, Gene Haislip, in response to McKesson's request for "guidelines on suspicious order reporting systems," it was noted that "the registrant should not merely be accumulating data on what appear to be excessive purchases for eventual submission to DEA, but rather that the system must be monitored so that any such orders will be apparent to the registrant and so that they can be reported to DEA upon discovery and, whenever possible, before the order is shipped."[338] The letter goes on to provide that the registrant cannot delegate its duty to identify suspicious orders to DEA by merely providing excessive order reports. The letter specifically states:

> A registrant, whose own personnel are in the best position to determine what is excessive or unusual based on knowledge of their customers and usual purchasing practices, may not abrogate its responsibility to identify suspicious orders and to determine whether to ship, or refuse to ship, the controlled substance order. The registrant must also report any suspicious orders as soon as possible to DEA. This has been conveyed to McKesson national management in San Francisco …[339]

Moreover, McKesson's own regulatory employees have acknowledged that this system did not flag true suspicious orders as required by the regulations. Multiple McKesson regulatory

[335] MCKMDL00450972 at 00450976.

[336] MCKMDL00450972 at 00450976.

[337] MCKMDL00450972 at 00451005-06.

[338] US-DEA-00026154.

[339] *Id.*

employees have acknowledged that the DU-45 reports were not meant to detect true suspicious orders. As discussed by McKesson's Regulatory Affairs Director, David Gustin, "the previous reports were not the exclusive and proper response to this regulation. We have an obligation to report 'suspicious orders.' With no clear definition of what constitutes a suspicious order we must rely on our own judgment as to what that is. If we report anything we believe to be truly suspicious we will be meeting the spirit and letter of the regulation. Simply reporting larger than usual orders does not when there are so many plausible and routine reasons for orders to be 'larger than normal.'"[340] Further, another Director of Regulatory Affairs for McKesson, Gary Hilliard, has testified that McKesson's suspicious order monitoring system prior to 2007 was not designed to detect true suspicious orders.[341]

Additionally, because during this time period McKesson was reporting excessive orders it had already filled it made no effort to detect, investigate, or block any suspicious orders. Consequently, during this time period McKesson blatantly violated the ***security requirement*** set forth in 21 C.F.R. § 1301.74(b).

b. **Policy Period #2 (May 2007-May 2008)**

McKesson's LDMP did not fare better when it came to identifying suspicious orders. McKesson has been unable to produce any documentation of true suspicious orders being reported during this time period.

c. **Policy Period #3 (May 2008-present)**

McKesson's CSMP could have been used as a tool to report suspicious orders, but was not used in that fashion until five years after it was initially launched. For Cabell County and Huntington customers, McKesson failed to report a single suspicious order from May 2008 to July 31, 2013.[342] This failure to report suspicious orders during this time frame is not an anomaly that is restricted to Huntington and Cabell County. As DOJ recognized, there was a "nationwide" and "systemic" failure of McKesson to report suspicious orders and otherwise maintain effective controls against diversion.[343] This conclusion is borne out by McKesson's failure to report any suspicious orders from its Livonia, Washington Courthouse, Lakeland, and Metheun distribution centers despite ample evidence of diversion occurring from customers of each of these distribution centers.[344] The egregiousness of McKesson's failure to report suspicious orders is further supported by the quantity of orders McKesson did report as suspicious once it finally decided to

[340] MCKMDL00510747.

[341] 1/10/19 Gary Hilliard Depo. at 176:8-176:22.

[342] MCKMDL01391127.

[343] MCKMDL00409453 at 00409454.

[344] *See generally* MCKMDL00409453.

begin engaging in the practice. For example, in 2015 alone, McKesson has acknowledged it reported a total of 230,000 suspicious controlled substance orders nationally.[345]

It is also apparent that McKesson's failure to report suspicious orders was not accidental or due to a misunderstanding of its regulatory duties. In fact, the term "suspicious" when it came to controlled substances was taboo within the company. At the time McKesson's CSMP was created in 2008 it included a section that advised employees to "[r]efrain from using the word 'suspicious' in communications" because "[o[nce McKesson deems an order and/or customer suspicious, McKesson is required to act. This means that all controlled substances sales to that customer must cease and the DEA must be notified."[346]

In fact, as late as 2015 McKesson continued to document its failure to identify and report suspicious controlled substance orders. In a document dated December 7, 2015, McKesson noted that for various reasons the company was failing to report approximately 1,500 suspicious controlled substance orders per month.[347]

Reporting Requirement:

McKesson failed to timely report suspicious orders in Huntington and Cabell County and nationally from at least 1997 to 2013. This is supported by the fact that McKesson's own regulatory employees have acknowledged that the excessive orders reported on the DU-45 reports were not synonymous with the type of suspicious orders outlined in the applicable regulations.[348] Moreover, even under the LDMP and CSMP McKesson continued its pattern of failing to report suspicious orders until finally beginning to do so in late 2013. But, as noted above, McKesson continued to fail to disclose significant numbers of suspicious orders at least through the end of 2015.[349] Finally, the number of suspicious orders reported in Huntington and Cabell County beginning on August 1, 2013 and continuing to December 2018 is insignificant compared to the number of opioid orders McKesson has filled during that same time period in those counties.

Further, using any of the methodologies as described in the Expert Report of Craig McCann, it is apparent McKesson failed to report thousands of suspicious orders arising out of the City of Huntington and Cabell County.[350]

Shipping Requirement:

[345] McKesson Board of Directors' Response to International Brotherhood of Teamsters at p. 24.

[346] MCKMDL00518064 at 005118078.

[347] MCKMDL02104903 at MCKMDL02104912.

[348] Deposition of Gary Hilliard, 176:8-176:22; MCKMDL00510747.

[349] *See e.g.*, MCKMDL02104903.

[350] *See* Section III above.

From at least 1997 to May 2008, McKesson failed to block any suspicious orders nationally. Due to its high thresholds for many customers, as noted above, McKesson has blocked an insignificant number of orders in Huntington and Cabell County after it began the practice in May 2008. It is apparent that McKesson's systems have not been designed to properly block suspicious orders given the miniscule number of suspicious opioid orders that have actually been blocked during that time frame.

C. AmerisourceBergen Drug Corporation

Distribution Center: Lockbourne, OH; Glen Allen, VA

DEA Registrant Number: [redacted]

Transactional Data Disclosed: Date range: 2002-2018[351]

Cabell County/Huntington Volume: [352]

Oxycodone	12,811,320 dosage units
Hydrocodone	22,630,590 dosage units

1. Court-ordered SOMS Discovery Disclosure:

- AmerisourceBergen Drug Corporation's Objections and Responses to Plaintiffs' (First) Combined Discovery Requests to Distributors (November 29, 2019);
- AmerisourceBergen Drug Corporation's Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests (February 26, 2020);
- AmerisourceBergen Drug Corporation's Second Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests to Distributors (March 10, 2020);
- AmerisourceBergen Drug Corporation's Objections and Responses to Plaintiffs' Second Set of Combined Discovery Requests (March 30, 2020);
- AmerisourceBergen Drug Corporation's Objections and Responses to Plaintiffs' Third Set of Combined Discovery Requests (April 8, 2020);

[351] *See* Bates Nos. ABDCMDL00037402; ABDCMDL00037404, ABDCMDL00037406; ABDCMDL00279848-279853; ABDCMDL00306728-306729; ABDCMDL00308071; ABDCMDL00313653-313654; ABDCMDL00316111-316114.

[352] McCann Report, App. 7.

- AmerisourceBergen Drug Corporation's Third Supplemental Objections and Responses to Plaintiffs' (First) Combined Discovery Requests to Distributors (April 17, 2020);

- AmerisourceBergen Drug Corporation's Objections and Responses to Plaintiffs' Fourth Set of Combined Discovery Requests (April 30, 2020);

- AmerisourceBergen Drug Corporation's Objections and Responses to Plaintiffs' Fifth Set of Combined Discovery Requests (May 8, 2020); and

- AmerisourceBergen Drug Corporation's Supplemental Objections and Responses to Plaintiffs' Third Set of Combined Discovery Requests (June 12, 2020).

2. **SOMS Corporate Policy Disclosed:**

a. *Pre-2007 Overview*

i. The Threshold-Based System

Beginning as early as 1990, AmerisourceBergen Drug Corporation ("ABDC") utilized a threshold-based system to determine if an order is "excessive" (i.e. suspicious). In the deposition of Senior Vice President of Corporate Security and Regulatory Affairs, Christopher Zimmerman described the threshold history of ABDC's Suspicious Order Monitoring System. Mr. Zimmerman began his employment with ABCS in 1990 and from the time he began his employment until 1998, the threshold was described as being calculated through the following procedure: "You take all the pharmacies within that category and divide by the number of pharmacies to come up with an average volume for the month per drug category. And then there was a multiplier of three. Any order that was over the threshold amount would be produced an excessive order report."[353] Mr. Zimmerman made a clarification to the threshold calculation by indicating the "3" multiplier was used for Schedule II and Schedule III narcotic drugs (ARCOS reportable) and a "6" multiplier, or maybe higher, was used for Non-ARCOS drugs.[354] Mr. Zimmerman stated the controlled substances identified during that time period were shipped prior to being reported to the DEA in the excessive purchase report.[355] Such a policy constituted a clear failure to maintain effective controls against diversion, as it entailed shipping controlled substance orders identified as suspicious (or in this case, "excessive"), was not designed to identify orders of unusual frequency, or those that deviated from normal ordering patterns. Further, this system improperly utilized a factor of "3" and "6" to establish thresholds well above the calculated average for ABDC's customers.

[353] *See* Zimmerman Deposition, 121:12-21.

[354] *Id.*, 124:18-125:5.

[355] *Id.*, 108:10-109:10.

During the time period of 1998 through 2007, ABDC implemented a new method of calculating thresholds. Mr. Zimmerman stated ABDC worked on a threshold project with the DEA for a two-year period from 1996 through 1998 to provide DEA with more accurate information. The threshold calculation was now calculated by using only a customer's four-month rolling average of that pharmacy's purchases and then applying a multiplier of three to "identify a trigger that would identify a suspicious order."[356] Again, such a policy constituted a clear failure to maintain effective controls against diversion because ABDC continued to ship controlled substance orders identified as suspicious. In addition, the system failed to identify orders of unusual frequency, or deviating from a normal pattern, used a much shorter time period for calculating the threshold which would allow the average to increase faster, failed to compare like pharmacies purchasing activity, and utilized a factor of "3" to establish threshold well above the calculated average for ABDC's customers.

ABDC's use of a threshold based system using a 3x multiplier derived from the DEA's Chemical Handler's Manual.[357] It is worth noting that these guidelines relate to "Listed Chemicals", rather than controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which multiples a monthly base weight average per base code by a multiplier (3x)]. Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. The Chemical Handler's Manual specifies that "when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicious. In addition to making the required reports, the transaction should not be completed until the customer is able to eliminate the suspicions. The distributor may have to forego some transactions."[358] Despite this directive from the Chemical Handler's Manual, ABDC did not consider foregoing such transactions at the time.[359]

Aside from the manner of calculating thresholds, ABDC's procedures for identifying suspicious orders and making decisions about whether to stop them were also improper. Multiple ABDC witnesses testified that ABDC used a DEA-approved system for reporting orders to the DEA and that the DEA-approved system allowed them to ship orders deemed to be suspicious and then report them to the DEA.[360] ABDC relies on letters from the DEA that they claim approve this system.[361]

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[356] *See* Zimmerman Deposition, 122:18-23.

[357] Id., 131:7-133:22.

[358] *See* Chemical Handler's Manual, 2001 Edition, at p. 21.

[359] *See* Zimmerman Deposition, 143:9-145:2.

[360] Depo. of Zimmerman (Vol. I) at 109-110; Depo. of Mays (Vol. I) at 85.,

[361] *See* ABDCMDL00269347.

As discussed above, and pursuant to what a policy summary generated by ABDC after 2015 describes as its "Legacy Diversion Control Program,"[362] ABDC shipped all orders of controlled substances before ruling out the possibility of the orders being suspicious.[363] Only after shipping the orders did ABDC report any orders that it deemed to be suspicious to the DEA through an "excessive order report."[364] ABDC sent these reports on a monthly basis to the DEA.[365] ABDC took no other actions with regards to excessive orders prior to 2005, meaning that ABDC shipped all orders - including orders that may have been suspicious – without any further investigation or due diligence.[366]

However, the testimony of ABDC's witnesses confirms that this practice actually violates the procedural portion of the system that the DEA allegedly approved.[367] Specifically, the earliest-produced SOMS policy and procedure document from ABDC in 1999 indicates ABDC's policy that "[b]ecause these procedures have been accepted by DEA, compliance with them is mandatory at all Bergen Brunswig Drug Company divisions."[368] The same document continues to explain that:

> If these customers' orders fit the suspicious order criteria explained above, you must contact the DEA to report the order ***before*** actually shipping the merchandise. This must be done even if you decide to cut the order back for business reasons. Again, in this case, it is the order that is suspicious, not the actual shipment.[369]

Here, ABDC's procedure of shipping before reporting does not comply with the procedure that was "mandatory" and allegedly approved by the DEA of shipping after reporting. As such, ABDC did not follow or comply with its own stated policies and procedures.

The determination of whether an order is "excessive" *i.e.* suspicious, has always been determined by ABDC using a threshold-based system.[370] ABDC deemed an order to be "excessive" if it exceeded a "threshold."[371] In order to create thresholds, ABDC generally identified characteristics by which it could group its customers (this analysis changed over time), then made certain determinations based on ordering patterns (this analysis also changed over time)

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[362] *See* ABDCMDL00004578-4602.

[363] *See* ABDCMDL00000109 ("Historically Controlled Substance/ Listed Chemical order monitoring has been based on a ship and report process.")

[364] *See* Zimmerman Deposition, 110:16-22, 121:7-122:3.

[365] *See* Mays Deposition, Part I, 101:7-24; *see also* Zimmerman Deposition, 108:19-24.

[366] *See* Mays Deposition, Part I, 142:15-143:14.

[367] Depo. of Zimmerman (Vol. I) at 109; Depo of Cherveny at 282.

[368] *See*, ABDCMDL00478320.

[369] *Id*. at ABDCMDL004478322.

[370] *See* ABDCMDL00004578, at 2-4, 7, 10-13.

[371] *See* Zimmerman Deposition, 121:7-21.

of its customers, and used that information to set a threshold of a drug that could be purchased without being deemed suspicious.

While documentation of ABDC's suspicious order monitoring program prior to 2005 is scant, Mr. Zimmerman testified that it involved a two-step process: "It was an excessive order report that was produced monthly to send to DEA, and then we also had a manual process at the distribution centers where the order fillers would identify suspicious orders and report those."[372] ABDC's written policies and procedures indicate that at least as early as December 1, 2005, ABDC operated an "Excessive/Suspicious Order Investigation Program," to "review the ordering activity of its customers to identify possible excessive or suspicious orders of controlled substances and listed chemicals."[373] Although the system now allegedly provided for the identification and investigation of excessive orders, ABDC's system still identified these orders using a threshold. Therefore, the 2005 system was not new, it merely continued the threshold-based system that was in place prior to the newly written policy. And, although ABDC conflated concepts of "excessive" orders and "suspicious" orders by treating them identically, ABDC continued its policy of shipping such orders to its customers, despite internally identifying them as either excessive or suspicious.[374] While the 2005 policy and procedures document includes a new "investigation" component that was not previously present in ABDC's suspicious order monitoring system, this component was effectively ignored because, as noted above, ABDC confirmed that it shipped all orders prior to 2007 without investigating them or reporting them to the DEA.

ii. Discretionary and Subjective Components of the Threshold-Based System

In addition to the excessive order reports which included orders that exceeded the relevant threshold, employees in ABDC's distribution centers ("DCs") were provided with guidelines instructing them to report orders that were of an unusual size or frequency, or which deviated from the normal ordering pattern.[375] ABDC placed signs in the distribution center "cages" with the base quantity levels that could be ordered, and it was left to a distribution center employee's discretion to determine whether an order was suspicious. ABDC's order monitoring system at the time also required that ABDC confirm whether customers had the appropriate licenses.[376]

At this time, ABDC employed the same monitoring policy across all of its customers, regardless of the type of customer, or whether they may have operated as "internet pharmacies."[377] Further, ABDC did not have any policies or procedures in place to compare its customers' purchase of controlled substances with the average purchases of similarly situated customers.[378] Rather,

[372] *See* Zimmerman Deposition, 108:19-109:4.

[373] *See* ABDCMDL00359957-9961.

[374] *Id*.

[375] *See* Zimmerman Deposition, 118:1-11.

[376] *See* Mays Deposition, 170-174.

[377] *See* Mays Deposition II, 57:16-58:15.

[378] *Id*., at 68:1-71:23.

ABDC only "monitored the average of each customer against its own orders at that time."[379] Nor did ABDC have any system in place to monitor its purchasing of Schedule II or III controlled substances as it compared to other types of substances,[380] or any system to evaluate the frequency of orders of controlled substances placed by its customers[381].

Prior to 2007, ABDC did not have a clear hierarchy establishing responsibility for preventing diversion. They did not form their Diversion Control Group or Team until after 2007.[382] This group was later referred to as the Corporate Security & Regulatory Affairs Department ("CSRA"). Aside from the baseline numeric thresholds, ABDC used to identify "excessive" orders, ABDC lacked clear objective standards for determining when orders from its customers were "suspicious." This was due, in part, to the fact that discretion was left to distribution center employees to gauge what constituted a normal ordering pattern and when a customer's order deviated from that pattern.

b. *Post-2007 Overview of the Order Monitoring Program (OMP)*

i. The June 2007 DEA Enforcement Action and Settlement

The year 2007 marks a key shift in ABDC's suspicious order monitoring policies. That year, the DEA initiated an enforcement action against ABDC due to its filling and shipment of orders from internet pharmacies, which according to the DEA, ABDC knew to be suspicious.[383] The enforcement action shut down and suspended the license of ABDC's Orlando distribution center. On June 22, 2007, ABDC and the DEA reached a settlement agreement regarding the Orlando distribution center, which acknowledged "AmerisourceBergen failed to maintain effective controls at the Orlando Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of AmerisourceBergen."[384] As a result, to obtain authorization from the DEA to re-open the Orlando facility, ABDC was forced to update its diversion control program, including adding (1) a more in-depth due diligence process; and (2) a requirement to stop shipping suspicious orders to customers.[385]

The settlement arose from failures in ABDC's suspicious order monitoring program, which were systemic because ABDC maintained uniform national suspicious order monitoring policies

[379] *Id.*, at 68:19-69:2.

[380] *id.*, at 72:1-5.

[381] *id.*, at 72:22-73:3.

[382] *See* ABDCMDL00270533.

[383] *See* ABDCMDL00269383-84.

[384] *See* ABDCMDL00279854.

[385] *See* Zimmerman Deposition, 139:20-140:8; *see also* Settlement and Release Agreement, ABDCMDL00279854–00279865.

and procedures.[386] According to an April 19, 2007 Order to Show Cause and Immediate Suspension of Registration issued by the DEA, ABDC distributed hydrocodone to pharmacies in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers, distributed hydrocodone to pharmacies even though they ordered small amounts of other drug products relative to those purchases, distributed hydrocodone to pharmacies much more frequently than ABDC's other customers, and shipped to pharmacies that ABDC knew or should have known many prescriptions were issued by physicians who did not conduct a medical examination of its customers, and instead wrote prescriptions for controlled substances ordered by customers over the internet.[387] Thus, the settlement between ABDC and the DEA resulted in nationwide changes to ABDC's suspicious order monitoring program. Specifically, ABDC revamped its procedures and instituted its Order Monitoring Program (OMP).[388] The most significant change was ABDC no longer shipped orders to customers that ABDC identified as being suspicious.[389] The OMP primarily relied on static thresholds to determine whether an order was potentially suspicious and should be investigated. If an order exceeded a threshold, it was flagged as an excessive or potentially suspicious order.[390] ABDC would not automatically designate an order that exceeded the threshold as "suspicious."[391]

ii. The New Threshold System

To determine each customer's threshold under the 2007 system or "Legacy Diversion Control Program," (otherwise referred to as the OMP) ABDC grouped customers within a "Customer Type."[392] The "Customer Types" were based on how customers were registered with the DEA, e.g. hospital/clinic, retail pharmacy, distributor, etc.[393] ABDC would then classify each customer by its "Customer Size," which was based upon its total average monthly total revenue of prescription sales of both control and non-controlled drugs (as opposed to its purchasing pattern of a specific drug family) relative to its peers in the same "Customer Type."[394] Customer Sizes

[386] *See* Mays Deposition II, 24:18-22.

[387] *See* ABDCMDL00269383-387.

[388] *See* generally ABDCMDL00000101.

[389] *See* ABDCMDL00270533.

[390] *See* Zimmerman Deposition, 112:18-113:2; 119:1-6. ABDC has claimed in deposition testimony that these were "orders of interest" beginning as early as 2007. However, deposition testimony from ABDC employee Kevin Kreutzer confirms that there was no use of that terminology during this time period. *See* Kevin Kreutzer Deposition, 67-68, 91-93, 109 ("Q. Do you recall Mr. Hazewski using the words "orders of interest" in 2009 when he trained you? A. No, I do not"), 111-12, 115-117). This inconsistency between the recollection of ABDC's employees undercuts the credibility of ABDC's witnesses.

[391] *See e.g.*, ABDCMDL00002405, 2411 ("Depending on certain circumstances, it may be deemed that order is suspicious."); s*ee also* Mays Deposition, 131:5-16.

[392] *See* ABDCMDL00000110.

[393] *Id.*

[394] *Id.*; *see also* ABDCMDL00002325.

were small, medium, large, or extra-large.[395] Then, ABDC looked at the Customer Type, and Customer Size and created an average purchase among of each drug family within each Customer Size and applied the same 3x multiplier. Implementation of the arbitrary 3x multiplier, however, negates the effectiveness of an effective Suspicious Order Monitoring System. Each customer had its own threshold for each drug family that it purchased, as described below, that was based on the foregoing analysis.[396]

If a customer's order exceeded a threshold, ABDC placed it in "OMP review."[397] After an order exceeded a threshold, all subsequent orders in the same family from that customer were rejected while the earlier order was in OMP review.[398] Each Distribution Center (DC) was responsible for "initial review of all orders in OMP review."[399] DC associates – sometimes referred to by ABDC as "responsible persons in charge" ("RPIC") – were initially responsible for this task. However, as ABDC's program evolved, this role eventually migrated up to the Distribution Center Compliance Managers. In 2007, the OMP allowed the DC associates to "review, release, or cancel potentially suspicious orders before they are shipped to customers."[400] Review at the DC level was based on "the knowledge of the customer and the order."[401] If the "DC can determine that the order is not suspicious, the DC will release the order," but if DC is unsure, the order will be flagged for investigation by members of the CSRA investigation team working under the Director of Diversion Control who were referred to as CSRA Investigators.[402] The CSRA personnel then would determine whether to report the order to DEA as suspicious. ABDC seemingly had no set, concrete rules or criteria for distribution center employees to determine what made an order of interest be elevated to CSRA or be released as not suspicious.[403] The DC associates maintained a number of different ways to resolve questions regarding orders. However, if a DC canceled an order (meaning that it would not be filled by the DC – with or without being reported to the DEA), or released an order (meaning it was approved for processing and shipped to the customer), the DC was required to log into the system with an explanation of why the action is being taken.[404]

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[395] *See* ABDCMDL00002405-2418.

[396] *Id.*

[397] *See* ABDCMDL00000114.

[398] *Id.*

[399] *Id.* The RPIC generally was responsible for the DC level review, although there was not a clear definition by ABDC of who was supposed to be in charge of reviewing orders at the DC level

[400] *See* ABDCMDL00002325.

[401] *See* Mays Deposition, 220:11-14; *see also* Zimmerman Deposition, 457:1-459:19.

[402] *Id.*; *see also,* ABDCMDL00046622.

[403] *See* ABDCMDL2405-2418 (describing the DC review process as "arbitrary"); *see also* ABDCMDL00250024-250063.

[404] *See* ABDCMDL00002325.

A customer who was repeatedly going over threshold or whose business was growing could request a "threshold review" to have its threshold adjusted. If approved, a threshold adjustment was referred to internally at ABDC as a "Threshold Override." The procedure for submitting a threshold review began when ABDC's sales teams, who were responsible for acquiring new customers and managing existing customers, submitted threshold review forms to the CSRA Department. The ABDC sales associate (from the sales team managing customer accounts) would request the threshold reviews for the customers.[405]

c. *FTI Consulting, Inc. Audit of ABDC Compliance Activities.*

In August 2015, ABDC voluntarily engaged an outside consultant – FTI Consulting, Inc. ("FTI") - to review its order monitoring system. FTI issued a report documenting the findings of an audit of ABDC's compliance activities.[406] The FTI report disclosed numerous problems, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies, and communications break-downs.[407] In addition to the report, for various areas within the company, including Diversion Control, a forty-five page chart discussed "findings & observations," "Gaps & Risks," and "Recommendations."[408] Notably, a "Gap & Risk" concerning ABDC's Diversion Control program included "[r]egulatory obligations related to diversion control."[409] David May, ABDC's senior director of Diversion Control, testified that in response to the report, ABDC took no actions and made no changes to its diversion policies or procedures.[410]

Despite this willful failure to address specific deficiencies in its OMP, evidence collected thus far shows that ABDC understands the importance of diversion control. For instance, David May testified that the company has "anti-diversion programs in place to prevent the misuse and abuse of controlled substances."[411] Similarly, Chris Zimmerman, ABDC's chief compliance officer, acknowledged, "if we don't adhere to our effective controls to prevent diversion, yes, diversion could occur."[412] As discussed above, however, the evidence shows that ABDC consistently ignored critical red flags and warning signs from its customers, which is a clear failure to maintain effective controls to prevent the diversion of controlled substances under the CSA, and which had real consequences in the communities where ABDC does business.

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[405] *See* Elkins Deposition, 245:2-246:6.

[406] *See* ABDCMDL00274105-18.

[407] *Id.*

[408] *See* ABDCMDL00250024-63.

[409] *Id.*

[410] *See* May Deposition, 149:2-5.

[411] *See* May Deposition, 97:22-98:1.

[412] *See* Zimmerman Deposition, 104:14-17.

For example, a DEA suspension order concerning one of ABDC's Ohio customers, East Main Street Pharmacy, documented deaths that occurred as a result of a failure to prevent diversion.[413] Ms. Julie Fuller, an ABDC sales representative who was responsible for East Main Street Pharmacy, testified in the suspension proceedings. Notwithstanding the obvious signs of illegal activity occurring at the East Main Street Pharmacy, including the fact that more than half of the pharmacy's prescriptions were written by an out-of-area doctor who was writing high volumes of controlled substances, Ms. Fuller "acknowledged that the purpose of her visits was not 'to observe [the pharmacist]' in the practice of pharmacy but to get his business."[414] Subsequent to the suspension proceedings, Ms. Fuller signed a Declaration, where she stated that as an account manager, ABDC only provided her general sales training, and did not provide any training or information on (a) how to identify questionable pharmacy behavior like suspicious dispensing, sales, or prescription filling practices, (b) how to report concerns regarding those behaviors, or (c) how to ensure that account managers only signed up and maintained accounts with legitimate pharmacies.[415]

The failure to conduct proper due diligence and maintain effective controls to prevent diversion is evident when examining compliance activity for ABDC customer Safescript Pharmacy #6 ("Safescript"), 335 4th Ave. in Huntington, West Virginia. Safescript was a customer of ABDC from 2006 to 2012. Safescript received the most opioid pills in Cabell County and was among the top five purchasers of oxycodone in West Virginia.[416] Safescript operated as a franchise retail pharmacy purporting to use proprietary technology for doctors (primarily pain management specialists) to transmit their prescriptions electronically to pharmacies as a means of reducing errors. Owner Kent Freeman, an Ohio resident, held licenses to operate locations in West Virginia, Kentucky, Tennessee, and other states. In May 2002, Freeman, the CEO of Safescript Pharmacies of Kentucky Inc., obtained a license to open and operate Safescript Pharmacy locations in Huntington, West Virginia, along with other locations in Kentucky and Tennessee.[417] Freeman was quoted, as planning to aggressively expand operations in the areas for which he purchased franchise rights.[418] In 2004, after Safescript became a customer of ABDC the SEC filed a complaint against the Safescript parent company for fraud, noting that Safescript's parent company inflated "reported revenue by selling franchise agreements to start-up franchisees in exchange for

[413] *See* https://www.deadiversion.usdoj.gov/fed_regs/actions/2010/fr1027_3.htm.

[414] *Id.*

[415] *See* Declaration of Julie Fuller, ¶ 9 (PLTF_2804_000004483).

[416] *See* https://www.herald-dispatch.com/news/million-opioid-pills-flooded-cabell-county-over-years-data-show/article_e617a338-1f1d-5600-80ba-ad0a3c81cd0d.html.

[417] See https://www.bizjournals.com/louisville/stories/2002/05/13/daily12.html (last visited August 3, 2020).

[418] *Id.*

worthless stock and promissory notes, and then immediately recognizing revenue from the transactions, despite the franchisees' known inability to pay."[419]

A review ABDC's Third Supplement Objections and Responses to Plaintiffs' (First) Combined Discovery Requests to Distributors revealed that ABDC submitted a very limited number of due diligence documents for Safescript. ABDC reported sixteen suspicious orders to the DEA detailed in the below chart.[420] There was either insufficient or no due diligence conducted by ABDC for the listed suspicious orders on the list. ABDC continued to distribute opioids, including the same type of drugs to Safescript after reporting suspicious orders to the DEA.

ABDC produced information related to sixteen suspicious orders placed by Safescript.[421]

Order Date	Allocated Dosage to Date	Held Dosage	Threshold	Quantity Ordered	Item Description	Item Unit Strength Quantity	Item Unit Strength Code	Item Size Quantity
20070717	27500	1000	22000	2	HYDROCOD/APAP	5/	500 MG	500
20070717	27500	2000	22000	4	HYDROCOD/APAP	10/	650	500
20080317	9200	2000	10000	20	METHADONE	10	MG	100
20080328	37600	600	30000	6	OXYCONTIN	80	MG CR	100
20080328	37600	1200	30000	12	OXYCODONE HCL	30	MG	100
20080328	37600	1200	30000	12	OXYCODONE HCL	15	MG	100
20091231	43800	300	45000	3	OXYCONTIN	80	MG	100
20091231	43800	200	45000	2	OXYCONTIN	20	MG	100
20091231	43800	300	45000	3	OXYCONTIN	40	MG	100
20091231	43800	100	45000	1	OXYCODE/ APAP	10/	325 MG	100
20091231	43800	2400	45000	24	OXYCODONE HCL	15	MG	100
20091231	43800	2400	45000	24	OXYCODONE HCL	30	MG	100
20100130	41000	300	45000	3	OXYCONTIN	80	MG	100
20100130	41000	200	45000	2	OXYCONTIN	40	MG	100
20100130	41000	2400	45000	24	OXYCODONE HCL	15	MG	100
20100130	41000	2400	45000	24	OXYCODONE HCL	30	MG	100

[419] *See* https://www.sec.gov/litigation/litreleases/lr18921.htm. (last visited August 3, 2020).

[420] ABDCMDL01911482.

[421] ABDCMDL01911482.

The first ABDC "SOM Investigation" into Safescript was dated June 20, 2007, and contained the following information:

> CSRA opened an inquiry in Safescript Pharmacy, account #010-052670 DEA registration [redacted] for excessive Hydrocodone purchases in 4/07. During 4/07 the customer purchased 21K dosage units of Hydrocodone with a 12-month average of 25K."
>
> This form has a date closed as of June 26, 2007, but also contains a comment under a heading titled, "Status," dated 3/28/2008, as follows: "Below response received from ACM – Scott, This account does a lot of this style of Medication. Several Pain Clinics in area. They did start buying from Miami Luken for a few months because we kept holding orders. They again started buying everything from us because the volume was going down and it was affecting their cost of goods. They always have done a lot with Oxy and Methadone and most likely always will. Thanks, Michael G. Perry.[422]

This same incident has an entry in LawTrac with a date entry of June 20, 2007, which contains the following:

> Safe Script Pharmacy is owned by Kent Freeman. Troy Whalen is the pharmacist in charge. The pharmacy has been a customer of ABC for approximately 4 years and does a monthly dollar amount of 190K. The percentage of sales which comes from controls is 38%. The pharmacy provided 3 physicians names and DEA #'s as prescribers of controls that they see scripts from. The Account Manager, Michael Perry, forwarded the CSRA Form 590 and photographs. I communicated with Mike Perry via telephone on 6/20 in reference to the account. Mike indicated that the pharmacy only has one walk up window due to security reasons and that the pharmacy sales very little OTC. Mike has been behind the counter of the pharmacy and has not observed anything suspicious. All information concerning an online search related to this account and completed Form 590c has been included in this file. Investigation does not indicate any type of diversion.[423]

ABDC has been unable to produce the CSRA Form 590 or Form 590c for Safescript, or photographs as described in the above paragraph.

A "SIM Investigation" was opened July 12, 2007, after Safescript orders were flagged for exceeding their threshold for Oxycodone purchases. The form contains the following notation:

> CSRA initiated an inquiry into Safescript #6, account #010-052670, as this customer was flagged on OMP for exceeding their threshold for Oxycodone Solid Family.

[422] ABDCMDL01911322-23.

[423] ABDCMDL01911371.

> This form has a dated closed of August 6, 2007, but contains the following entry under the status heading with a date of May 10, 2013: Threshold review request received. All pertinent information attached.[424]

This same incident has an entry in LawTrac with an entry date of July 12, 2007, which contains the following:

> After further review of this customer it was discovered that a site visit and Form 590 had previously been completed under RA07-1051. The customer was cleared under that investigation and the order in question appeared to be along the normal purchasing pattern. At the time of the previous investigation, the customer's purchase volume was 190K. The percentage of RX purchases that constitutes controls was 38%. No indication of diversion; order was released.[425]

Later, in October 2007, ABDC ran another report on Safescript's purchasing pattern and discovered the controlled to non-controlled substance purchasing ratio was actually 61.99%.[426] And, this ratio continued to increase over time. In 2008, the controlled to non-controlled substance purchasing ration increased to 85.9%.[427]

On July 29, 2011 Account Manager Michael G. Perry submitted a form titled, "Request for Threshold Review" to Ed Hazewski CSRA Diversion Control Manager requesting a review of "Oxycodone (All Oxycontin)" with the following explanation: Ed, this customer and has had issues with them exceeding the thresholds on these items. Please review and see if we can up the thresholds on these items. Please see additional information in the email, Thanks, Michael G. Perry (ACM).[428]

Further review of history between ABDC and Safescript indicates similar inattention to due diligence in the face of orders exceeding threshold and an ever-increasing ratio of controlled substance purchases compared to non-controlled substances. Between 2007 and 2012 ABDC "investigated" a total of 589 order lines from Safescript, 214 of which were released, and 41 were reported to the DEA.[429] In multiple instances, lines of orders for similar or identical products were approved within days of a reported order.[430] Examples of "due diligence" like the documents submitted to justify a threshold increase cited above do not provide sufficient due diligence to maintain effective controls to prevent diversion when investigating orders or requests to increase thresholds for opioids.

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[424] ABDCMDL01911302-303.

[425] ABDCMDL01911363.

[426] ABDCMDL00313879.

[427] ABDCMDL00360324.

[428] ABDCMDL01911300; ABDCMDL08021654 and ABDCMDL08026156.

[429] ABDCMDL01911482; ABDCMDL01911481.

[430] *Id*.

A year-over-year analysis shows sales to Safescript increasing 37% in one year, driven largely by sales of oxycodone and methadone. Increases in benzodiazepines are also present.[431]

Drug Family	Mar-May 2008	Mar-May 2009	Increase	% Increase	% Total Sales Increase
Benzodiazepine	55,520 du	60,720 du	5,200 du	9%	37%
Hydrocodone	52,200	58,000	5,800	11%	37%
Methadone	32,900	51,400	18,500	56%	37%
Oxycodone	92,600	119,700	27,100	29%	37%

Safescript's ratio of controlled substances purchases compared to non-controlled substances also provided ABDC with reason to be concerned. Over time, Safescript's controlled substance purchases accounted for 87% of its total purchasing from ABDC.[432] Not surprisingly, in November 2011, Safescript appeared on a list of the "top 100 purchases of OX products among food/chain/independent customers."[433] Correspondence from ABDC's Ed Hazewski indicates that he knew that customers on the list were "servicing" pain doctors without "specializing" in pain management, and that they "overwhelmingly" purchased oxy 30 without having a varied product mix.[434] At this time, Safescript was purchasing a monthly average of 36,500 dosage units of oxycodone. In July 2011, ABDC's Michael Perry requested a threshold increase for oxycodone produces on behalf of Safescript because Safescript "has had issues . . . exceeding thresholds on these items. Please review and see if we can up the thresholds on these items."[435]

Against this backdrop, ABDC continued to service Safescript unabated until February 2012 when Safescript's owner was charged with a drug trafficking charge under state law.[436] Safescript was placed on ABDC's "Do Not Ship List" February 13, 2012, with a notice citing a "CSRA investigation" but not the owner's arrest.[437] It is unclear from ABDC's records whether this had any effect on Safescript's ability to purchase controlled substances. In the intervening months, multiple "OMP Threshold Overrides" were placed on the pharmacy for various drug families, and the "business cancellation date" for Safescript was not entered until December 17, 2013.[438]

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[431] ABDCMDL00170136.

[432] *See*, ABDCMDL00170213.

[433] *See*, ABDCMDL00280699, ABDCMDL00280700.

[434] *Id*.

[435] *See*, ABDCMDL01911300.

[436] Hessler, Courtney, "65 million opioid pills flooded Cabell County over 7 years, data show," *Herald Dispatch*, July 19, 2019, https://www.herald-dispatch.com/_recent_news/more-than-65-million-opioids-flooded-cabell-county-over-7-years-data-shows/article_8f0d8676-a9a9-11e9-98ff-ebdd2586af3f.html. (last visited August 3, 2020).

[437] *See*, ABDCMDL00047800.

[438] *See*, ABDCMDL00353569; ABDCMDL00171203.

In contrast to ABDC's due diligence record on Safescript, news reports regarding the investigation into Safescript and its owner indicate that the investigation began in 2009 and involved 183,000 unaccounted pain pill doses according to the West Virginia Board of Pharmacy.[439] After Freeman's arrest, news reports described Safescript in suspicious terms - contrary to Michael Perry's portrayal. Customers said it was not a "usual pharmacy" – they did not sell "bandages or back braces," only prescriptions. This corresponds with internal ABDC notes from 2007, which stated the pharmacy did not sell a lot of OTC products.[440] However, media coverage of the arrest also described how the facility had "heavy security and no contact – working behind what they say appears to be bulletproof glass" as well as transactions being done through a "turnstile" where customers would "put money in and the pills come out."[441] Michael Perry's description of Safescript omitted these details when he described being "behind the counter of the pharmacy" and not "observ[ing] anything suspicious."[442]

3. **Suspicious Orders Reported In Huntington and Cabell County Jurisdictions**[443]

	Pre-Shipment Reporting	Post-Shipment Reporting
2007	2	0
2008	4	0
2009	12	0
2010	5	0
2011	1	0
2012	4	0
2013	11	0
2014	6	0
2015	0	0

[439] *See*, https://www.wsaz.com/home/headlines/Huntington_Pharmacy_Under_Federal_Investigation_139861153.html.

[440] ABDCMDL01911371.

[441] https://www.wsaz.com/home/headlines/Huntington_Pharmacy_Under_Federal_Investigation_139861153.html.

[442] *See*, ABDCMDL01911371.

[443] *See* ABDCMDL01911479; ABDCMDL01911482.

2016	0	0
2017	0	0
2018	0	0

4. **Due Diligence Conducted**

On August 10, 2005, the DEA met with Steve Mays, ABDC's then-Director of Regulatory Affairs, to inform him about the common characteristics of pharmacies that divert large amounts of controlled substances by filling invalid prescriptions obtained by customers using the internet.[444] Prior to that meeting, ABDC's due diligence policy consisted solely of "a good faith effort to make sure that that customer's properly licensed with the state and registered with the DEA."[445]

As a result of the 2005 DEA meeting, ABDC began using a questionnaire to obtain information about its customers as part of a new due diligence effort, which consisted of 10-12 questions, but they were "all related to internet pharmac[ies]."[446]

After the 2007 DEA enforcement action, ABDC implemented a "Know Your Customer" due diligence policy. ABDC's due diligence program was effectuated through the Form 590 retail pharmacy questionnaire. The Form 590 was supposed to be filled out by ABDC's customer sales representatives in conjunction with ABDC's pharmacy customers. ABDC's witnesses testified that the Form 590 is and was an important component of its diversion control program.[447]

The Form 590 process, however, suffered from numerous deficiencies. First, for many years, the Form 590 was only for new customers.[448] None of the requisite due diligence information was collected for existing customers.[449] Additionally, ABDC exempted "retail chain pharmacies" (broadly defined to include pharmacies with 10 or more locations, or any number of locations in more than one state) from the Form 590 requirement.[450] Rather than require all pharmacies within a chain to complete a Form 590, ABDC allowed the chain to complete one Form 590. This exempted large swaths of ABDC's customers from the requirement of completing Form 590.

Moreover, documents show that even when Form 590s were required, vast numbers of the forms were either illegibly filled out or contained substantial omissions.[451] Indeed, David May

[444] *See* ABDCMDL00269383-387.

[445] *See* Mays Deposition II, 73:24-74:21.

[446] *See* Mays Deposition 134:16-135:16; Mays Deposition II, 37:1-15.

[447] *See, e.g.*, May Deposition, 263:8-19.

[448] *See* Zimmerman Deposition, 213:10-17.

[449] *Id.*

[450] *See, e.g.*, ABDCMDL00000107; *see also*, Zimmerman Deposition, 213:16-214:9.

[451] S*ee* May Deposition, 269:12-20.

acknowledged that the "continued deficiency [in the Form 590s] puts us at risk with regulators."[452] In 2016, ABDC implemented a "CSRA 590 Validation Project" to "validate that all ABDC customers authorized to purchase controlled substances and identify any with deficiencies"[453], but one year into the project, ABDC had only received "about 10% percent of the required customer due diligence documents."[454] To date, as of May 29, 2018, ABDC estimates that only about 60% of the due diligence deficiencies have been remedied.[455] The lack of both current and historical documentation of due diligence efforts are indicative of a failure to maintain effective controls to prevent diversion.

In 2013, ABDC's due diligence efforts were the subject of a DEA audit and subsequent investigation. According to Joseph Tomkiewicz, an investigator and diversion program manager at ABDC, DEA agents met him at his personal residence sometime in the fall of 2013. This resulted in conversations with the U.S. Attorney about ABDC's due diligence efforts, specifically whether it had truncated the Form 590 for a specific group of pharmacies, which investigators believed may have short-circuited ABDC's customer due diligence process.[456] This point is also reflected in an ABDC "DEA Audit History" spreadsheet, with notes that indicate: "DEA was not comfortable with the [OMP] program and analyzed the program specifically how customers are screened."[457]

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by ABDC has fallen short. First, ABDC conducted no due diligence until 2005. Once a due diligence program was finally instituted, it consisted of merely a short questionnaire and checking to confirm that the customer's licenses were current. Moreover, ABDC's initial due diligence program only addressed internet pharmacies. Later, even when the due diligence was conducted more broadly, it focused on new customers and, like some other wholesale distributors, ABDC regularly showed complete deference to chain pharmacies. Therefore, the due diligence for those customers was consistently lacking. Finally, more recently, it was uncovered that ABDC did not have any of the requisite due diligence files for significant numbers of its customers, calling into question whether any due diligence was actually conducted. In my opinion, while ABDC has had some sort of due diligence program in place since 2005, a review of those programs in practice makes clear that for all practical purposes, ABDC's due diligence efforts have fallen short of what is required.

[452] *See* ABDCMDL00159415.

[453] *Id.*; May Deposition, 272:8-13.

[454] *Id.*, at 273:21-24.

[455] *Id.*, at 283:24-284:23.

[456] *See* Tomkiewicz Deposition, 35:10-23; 57:2-16:14; *see also* WAGMDL00237263.

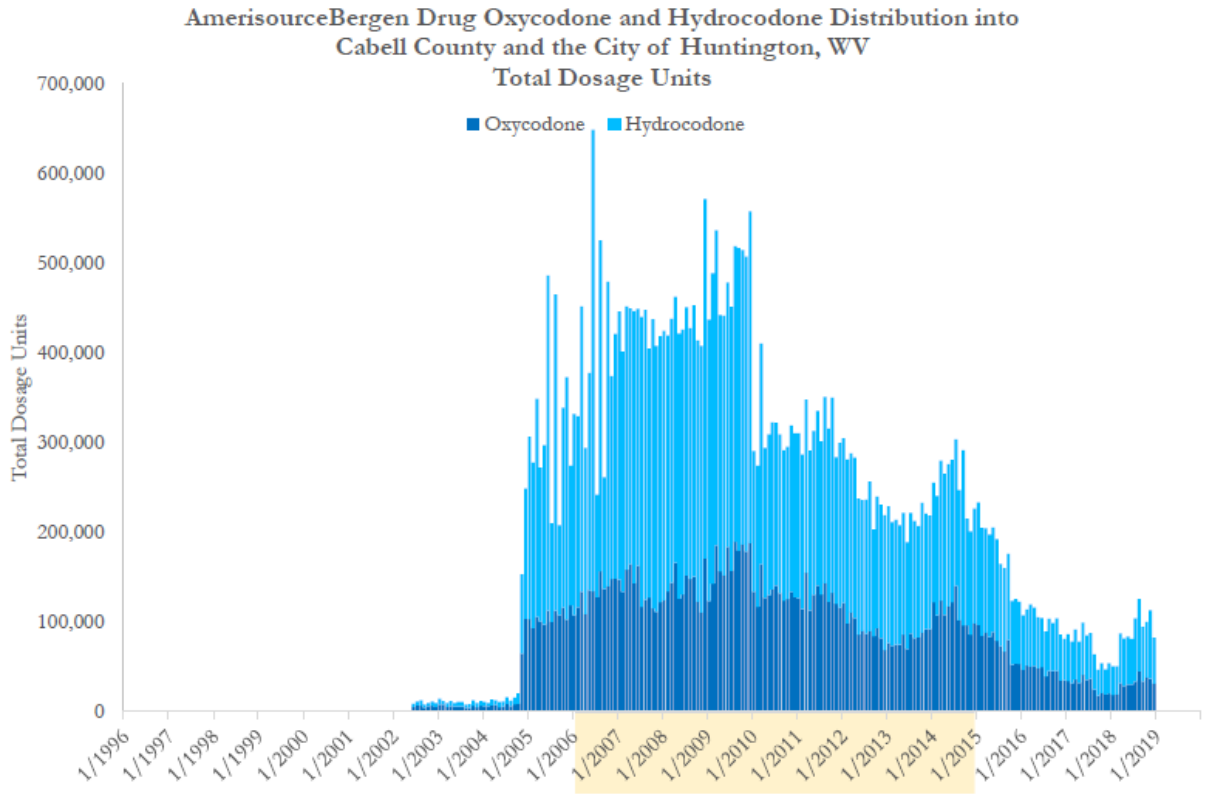
[457] ABDCMDL00253869.

5. **Opinions Related to AmerisourceBergen**

a. **AmerisourceBergen failed to maintain effective controls against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].**

The graphs below demonstrate a clear escalation of prescription oxycodone and hydrocodone by AmerisourceBergen into Cabell County and the City of Huntington by dose, base weight, and MME.[458]

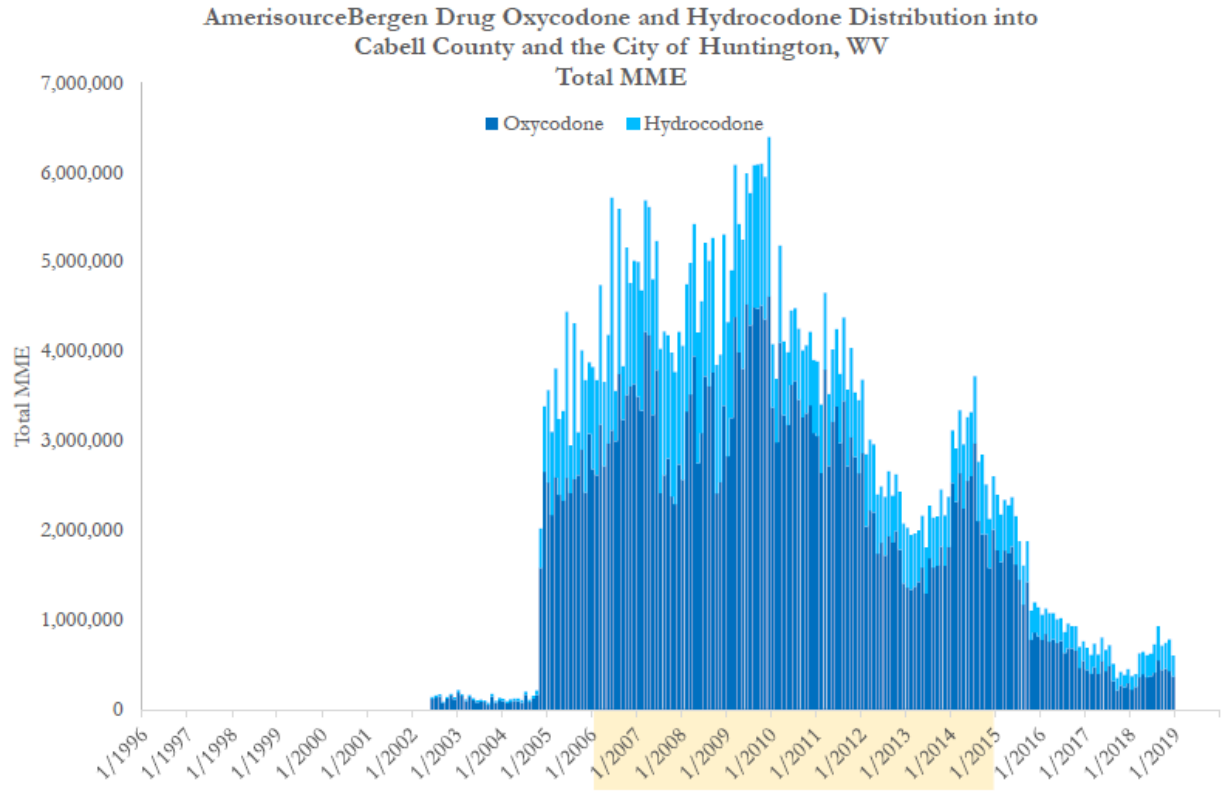
Region: Cabell County and the City of Huntington, WV
Time: 6/2002 - 12/2018
Seller: AmerisourceBergen Drug
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (ABDC 6/2002-12/2018)

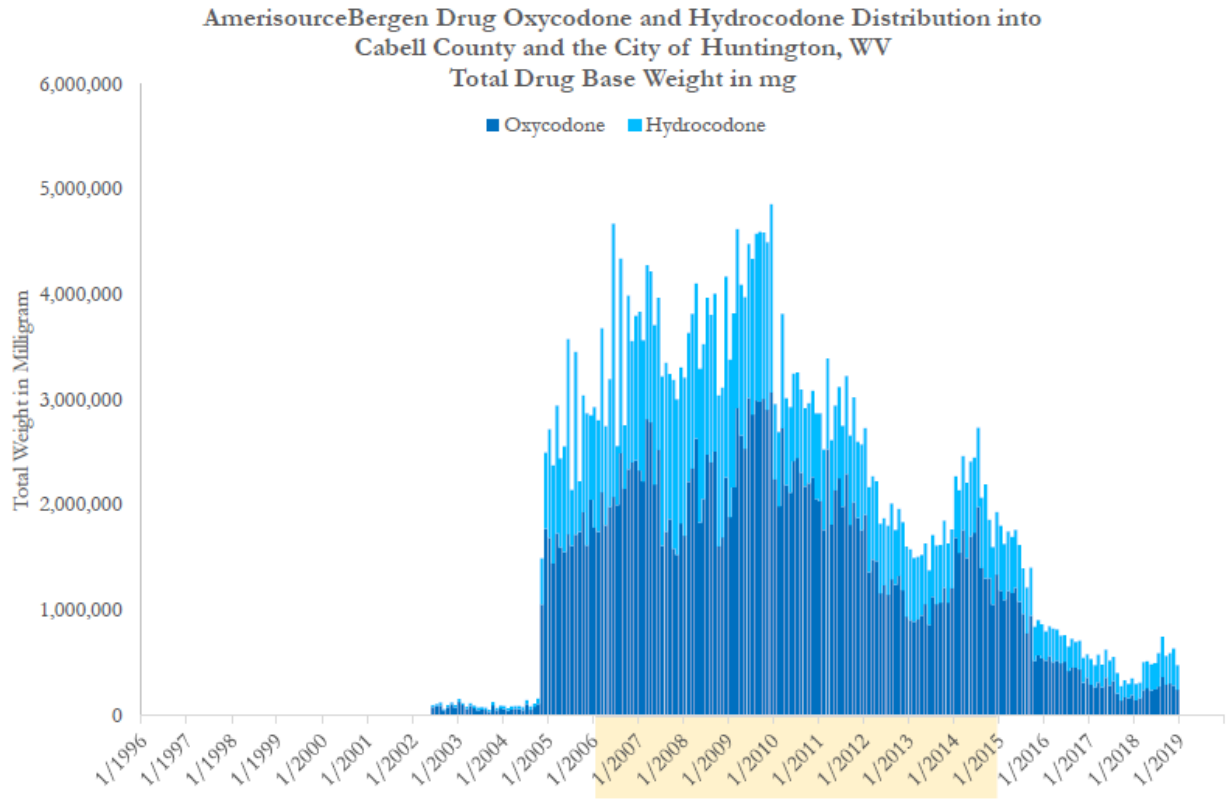
[458] McCann Report, App. 9(C).

Region: Cabell County and the City of Huntington, WV
Time: 6/2002 - 12/2018
Seller: AmerisourceBergen Drug
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (ABDC 6/2002-12/2018)

Region: Cabell County and the City of Huntington, WV
Time: 6/2002 - 12/2018
Seller: AmerisourceBergen Drug
Buyer: All Dispensers
Drug: Oxycodone and Hydrocodone



Data source: ARCOS (2006-2014) and Defendant Transactional Data (ABDC 6/2002-12/2018)

Documents produced by ABDC show that rather than focusing on putting effective controls to prevent diversion in place and designing and operating a system to detect suspicious orders and stopping those orders ABDC circumvented the requirements and coached customers on how to avoid being detected by the system and being the subject of an enforcement action by the DEA. For example, a July 2013 ABDC document entitled "Sales Talking Points" stated as follows:

> I am rather concerned about your pharmacy for a different reason. Based on your overall volume with us, your percentage of C2 orders is high and may be deemed suspicious by either our OMP system or regulatory authorities. ***This puts your account with ABDC at significant risk of closure or exposure to regulatory and enforcement agencies actions.***
>
> Every day, we read about another independent pharmacy under investigation. ***I want to make sure that doesn't happen to you.*** The way I see it, is that you have a couple of options. First, you can make ABDC your primary wholesaler and shift all purchases to us. The second option is we arrange a short-term transition process and you stop buying C2s from ABDC and shift them to whomever your buying

other products. The third option would be to do nothing -- but this is not a feasible long-term decision -- and its not a good option for anyone.[459]

b. **AmerisourceBergen failed to stop shipments of suspicious orders of controlled substances in violation of the requirement to maintain effective controls against diversion as set forth in 21 U.S.C.A. § 823(b)(1) [1970].**

ABDC's official national policy from 1990, up until the DEA Settlement in 2007, was to ship all orders of controlled substances, regardless of size, frequency, deviations from prior orders, deviations from averages, deviations from defined thresholds, or whether that order was determined to be suspicious. This is a blatant violation of the No-Shipping Requirement.

c. **AmerisourceBergen failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the *security requirement* set forth in 21 C.F.R. § 1301.74(b).**

Pre-2007, ABDC's suspicious order monitoring system failed the security requirement set forth in 21 C.F.R. § 1301.74(b). Specifically, ABDC's pre-2007 policies constituted a failure to design and operate a system to identify suspicious orders because they only identified "excessive" orders that exceeded a 3x threshold, which only took into consideration prior orders of that specific pharmacy. ABDC's OMP system did not take into consideration other relevant factors such as order frequency patterns, order averages of similar pharmacies, or comparisons of sales of Schedule II or III controlled substances with the sales of other controlled substances. ABDC also had no meaningful due diligence process in place to investigate whether such "excessive" orders otherwise qualified as suspicious, other than an effort to make sure a customer was licensed with the state and registered with the DEA. As evidenced by the 2007 DEA Enforcement Action which suspended the registration of ABDC's Orlando distribution facility, ABDC also specifically failed to identify suspicious orders from internet pharmacies that the DEA concluded should have been identified.

Post-2007, ABDC failed to design and operate an adequate system to identify suspicious orders because it continued to employ a "threshold-based system," which was based on an arbitrary "3x multiplier" among drug families, which again ignored other relevant information. ABDC also left critical discretion to identify suspicious orders with its distribution center employees, without putting in place any set, concrete rules or criteria on how suspicious orders should be identified. The 2015 FTI Audit Report also revealed numerous problems with ABDC's system, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies, and communications break-downs, which contributed to "gaps and risks" in ABDC's ability to identify orders as suspicious and prevent diversion. ABDC's efforts of due diligence in identifying suspicious orders at this time also fell well short of effective. Specifically, the "Know Your Customer" due diligence policy was based on a form filled out by ABDC's own sales representatives in conjunction with ABDC's pharmacy

[459] ABDCMDL00278212 (emphasis added).

customers, creating a conflict of interest in identifying accurate information. The fact that ABDC's chain retail pharmacy customers were exempt from this requirement abdicated ABDC's duty to identify suspicious orders to the customers themselves. Further, the Form 590 due diligence program itself was inconsistently implemented, leaving a lack of current and historical documentation of due diligence efforts that renders a robust, effective due diligence system impossible.

d. **AmerisourceBergen failed to *report* suspicious orders of controlled substances in violation of the *reporting requirement* set forth in 21 C.F.R. § 1301.74(b).**

Between 1998 and 2008, AmerisourceBergen timely reported zero suspicious orders from the CT1 jurisdictions. This is a blatant violation of the Reporting Requirement. Further, using any of the methodologies described in the Expert Report of Craig McCann, it is apparent AmerisourceBergen failed to report thousands of suspicious orders arising out of Huntington and Cabell County.[460]

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct.

Date: August 3, 2020

James E. Rafalski

[460] *See* Section III above.